Instructions for Accessing IMS via Commons Status

System Version 1.11.4.11

Document Version 1.4.2

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CONTACT US

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For general questions about this module and associated business processes:

Please contact your IC Coordinator. A list of IC Coordinators is available online:

http://inside.era.nih.gov/techrep_list.cfm.

Troubleshooting support:

Please contact the eRA Service Desk:

Toll-free: 1-866-504-9552

Phone: 301-402-7469

TTY: 301-451-5939

Web: https://inside.era.nih.gov/eRA_helpdesk.cfm (Preferred method of contact)

Email: commons@od.nih.gov (for Commons Support)

Email: helpdesk@od.nih.gov (for IMPAC II Support)

Hours: Mon-Fri, 7:00 a.m. to 8:00 p.m. Eastern Time

DISCLAIMER STATEMENT

No data shown in illustrations represents any real account, project, or individual. Any resemblance to actual accounts, projects, or individuals is purely coincidental.

DOCUMENT HISTORY

Date	System Version	Document Version	Description of Change	Author
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May 17, 2016	1.11.2.2	1.4.0	Updated field names and screenshots, IDR Attributes screens.	eRA Communications
December 15, 2016	1.11.3.1	1.5.0	Updates related to Final Budget Period and Final RPPR	eRA Communications

The most current version of this document will be available on the eRA website: http://era.nih.gov.

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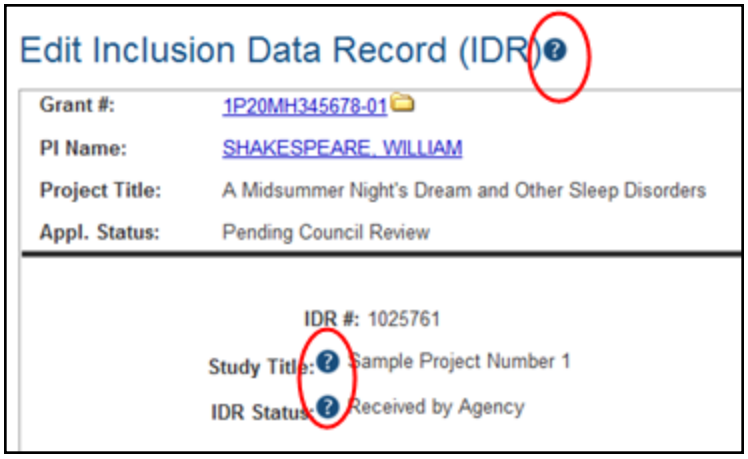
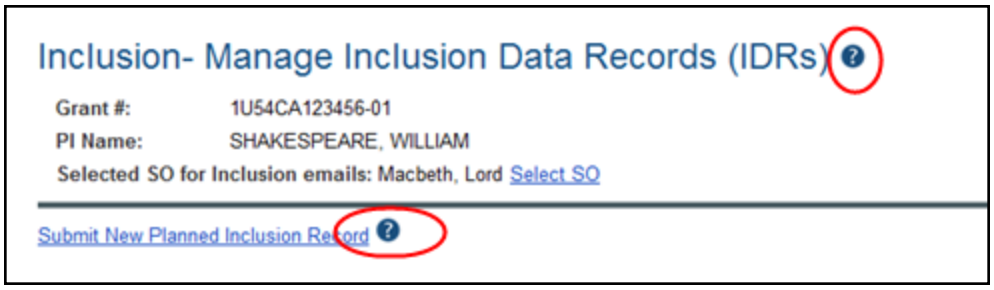
5 Welcome to the IMS Online Help

This online help provides information about Inclusion Management System (IMS) functionality including step-by-step instruction for completing tasks.

You can access the online help by selecting any help icon located on many of the screens within IMS. You can find most of the icons next to the screen titles. These icons will take you to the help topic specific to the IMS screen you came from, but you can always search for other topics and navigate through the entire online help as needed.

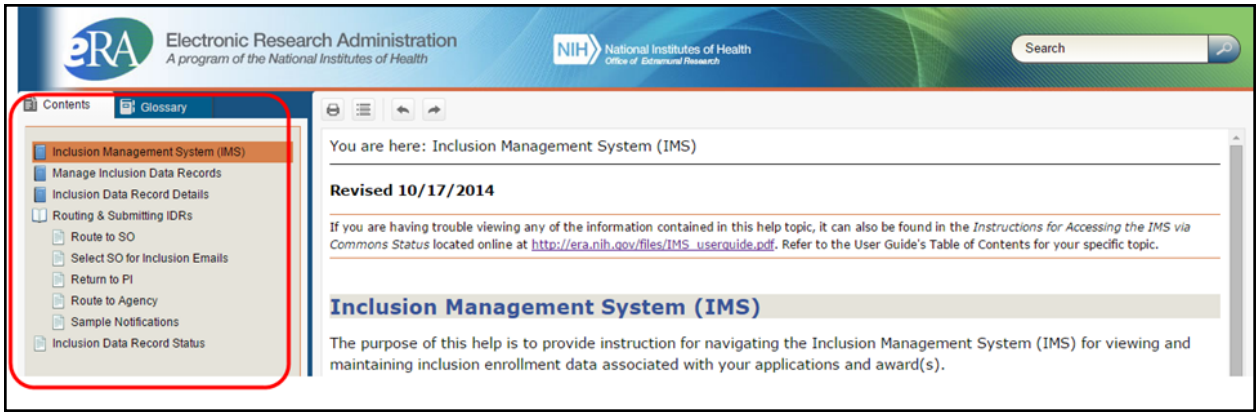




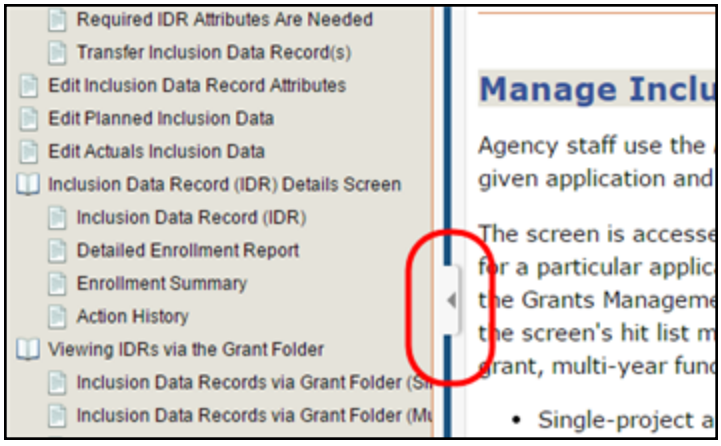
Use the following options to navigate the online help:

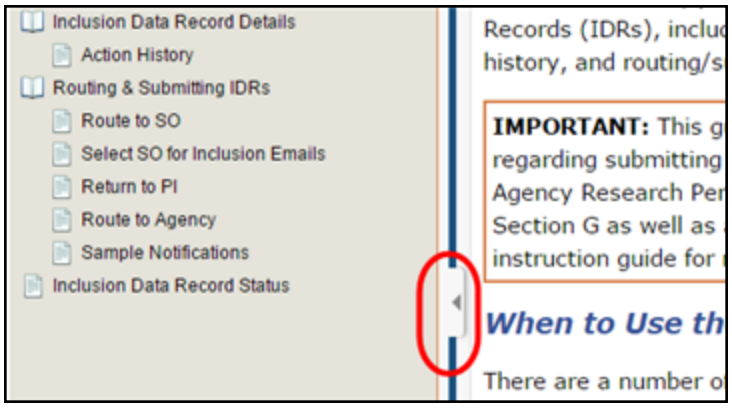
5.0.1 Contents Tab

The **Contents** tab displays books and pages that represent the categories of information in the online help. Click a closed book to open it and display sub-books and pages. Click an open book to close it. Click on a page to view it in the right-side pane.

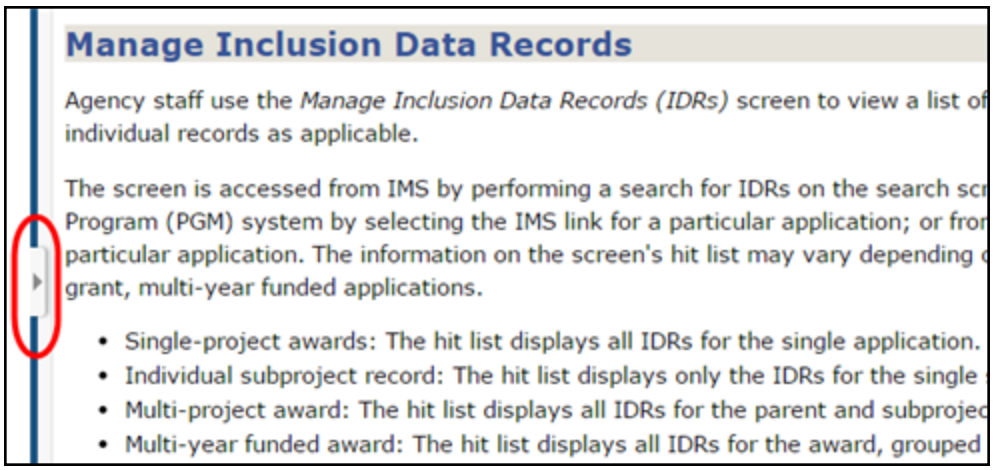


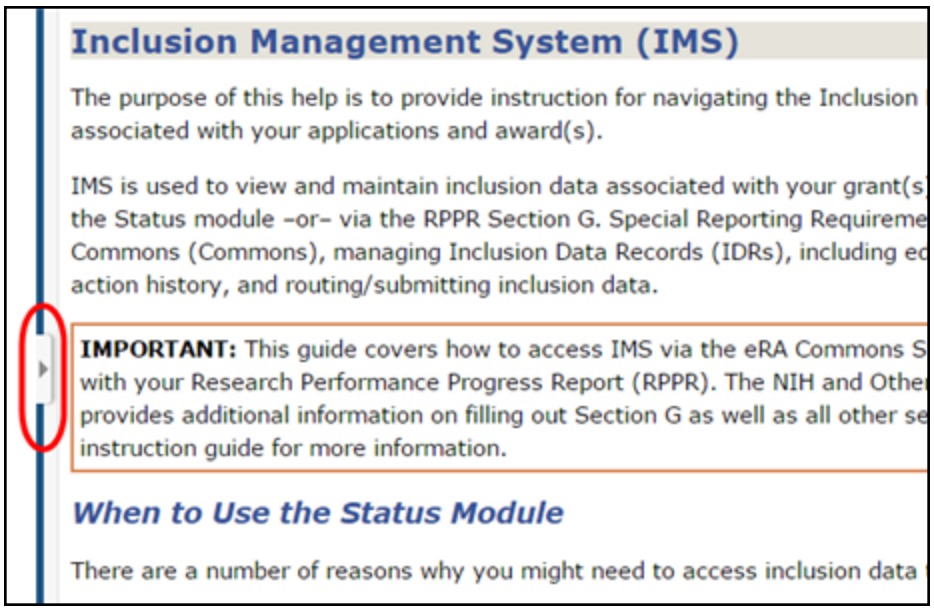
If you'd like to see the topic across the entire screen, you can hide the **Contents** pane by clicking on the arrow located midway down the right side of the pane.





Unhide it by selecting the arrow again.





5.0.2 Print Button

The **Print** button enables you to print the topic located in the right-side pane. Any collapsed information within the topic will not be included in the print-out. To include all information, make sure to use the **Expand All** button before printing.

5.0.3 Expand/Collapse All Button

The **Expand/Collapse All** button allows you to expand and collapse hidden information (e.g., images) within the current topic.

5.0.4 Navigate Previous Button

The **Navigate Previous** button allows you to view the previous topic in the list of Contents.

NOTE: Use the **Back** button on your browser to view the topic you previously viewed.

5.0.5 Navigate Next Button

The **Navigate Next** button allows you to view the next topic in the list of Contents.

5.0.6 Search Button

The **Search** button enables you to search for terms and locate topics containing these terms. Once the search is complete, a list of topics appears so you can select a specific topic to view. This search feature retrieves information only from the Inclusion Management System (IMS) online help.

5.0.7 Togglers

Togglers appear in blue text with an arrow and are used to expand or collapse hidden information, such as screen images or additional text within the help topic. Click this toggler to display (expand) or hide (collapse) the information.

You've just untoggled this information!

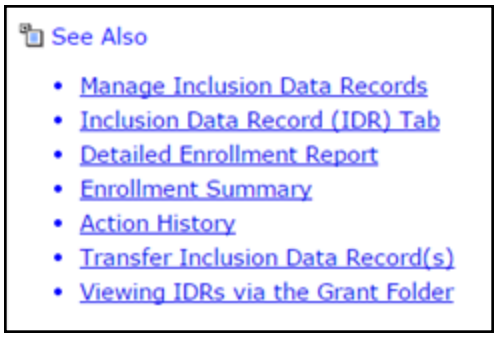
5.0.8 Links

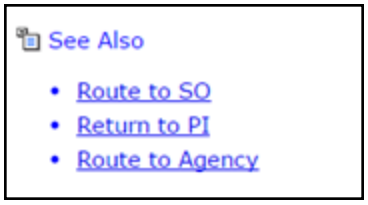
Links appear in blue, underlined text and direct you to related help topics or to online information outside of the online help. Clicking a link displays the information in a new window.

NOTE: After selecting a link for the first time, it will appear as purple, underlined text.

5.0.9 See Also Content

A **See Also** list of related topics contains individual links to other topics in the online help related to the topic currently being viewed. Select the link of the appropriate topic to view that topic. The selected topic will open in a new window.



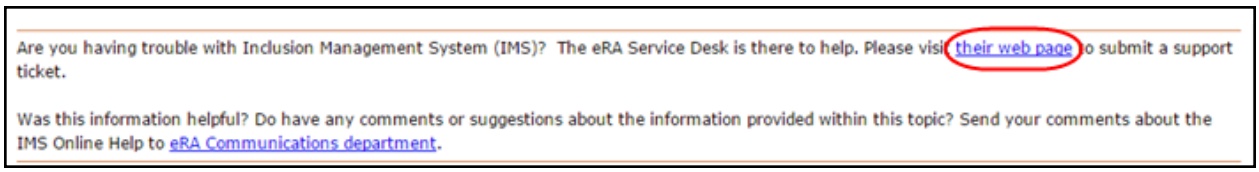


5.0.10 Contact Us

Links are provided in the footer of every topic to easily contact eRA.

Are you having system issues? Use the link in the footer to access the eRA Service Desk online ticketing system at which you can submit a ticket for support and find other means of contacting eRA Service Desk.

Do you want to provide feedback about the topics found in this online help or its corresponding user guide? Use the **eRA Communications department** link to contact eRA Communications, the author of this content.



5 Latest Updates

5.1 September 29, 2016

- PIs can now edit IDR forms submitted through eSubmission when only cumulative enrollment data is provided. For instructions on editing IDRs see Edit Inclusion Data Record (IDR) Attributes.

5.2 May 12, 2016

- IDR Attributes screen — Participant Location field is now called Enrollment Location on all IDR screens. See Edit Inclusion Data Record (IDR) Attributes.

5 Inclusion Management System (IMS)

The purpose of this guideonline help is to provide instruction for navigating the Inclusion Management System (IMS) for viewing and maintaining inclusion enrollment data associated with your applications and award(s).

IMS is used to view and maintain inclusion data associated with your grant(s) and can be accessed in one of two ways, both through the eRA Commons system: via the Status module –or– via the RPPR Section G. Special Reporting Requirements. In these instructions, you will find information on accessing IMS via the eRA Commons (Commons), managing Inclusion Data Records (IDRs), including editing planned inclusion data, editing cumulative inclusion data, viewing IDR details and action history, and routing/submitting inclusion data.

IMPORTANT: This guide covers how to access IMS via the eRA Commons Status module. It does not cover information regarding submitting your inclusion data with your Research Performance Progress Report (RPPR). The NIH and Other PHS Agency Research Performance Progress Report (RPPR) Instruction Guide provides additional information on filling out Section G as well as all other sections of the progress report. Refer to Chapter 5.2.4 and Chapter 6.7 of the RPPR instruction guide for more information.

5.3 When to Use the Status Module

There are a number of reasons why you might need to access inclusion data through Commons Status rather than through your progress report. For example:

- Before award of a competitive application, changes may be necessary to the inclusion data submitted with the application via Grants.gov.
- Post-award, there may be a requirement to provide more frequent updates to inclusion enrollment in addition to any reporting associated with the RPPR.

Inclusion data cannot always be updated using Status. When application is undergoing peer review, the inclusion data is not accessible in the Inclusion Management System. Also, after a grant is awarded, only the View links will be available for the IDRs associated with fiscal year award. The data for a given fiscal year is locked when the award is issued and no further updates can be made. At that point, you can make updates via Status for the record associated with the next fiscal year.

You will also be blocked from using Status to update inclusion data after the progress report for the fiscal year has been initiated and changes to the inclusion data have been submitted and saved in the system via the Inclusion link in the progress report.

For more information about the progress report see the NIH and Other PHS Agency Research Performance Progress Report (RPPR) Instruction Guide.

5.4 Access via Status Module

This topic covers how to access IMS via Status. It does not cover additional information regarding the Status module. For more information on the Status module, refer to the topics Status for Program Directors/Principal Investigators (PI Role) and Status for Signing Officials (SO) role in the Commons Online Help.

Also, the Commons Status module looks and behaves differently for different users, depending on their Commons role (e.g., PI, SO). Therefore access to IMS via Status also differs depending on whether you are a Principal Investigator (PI) (or delegate) or a Signing Official (SO). See the instructions below for your specific Commons role.

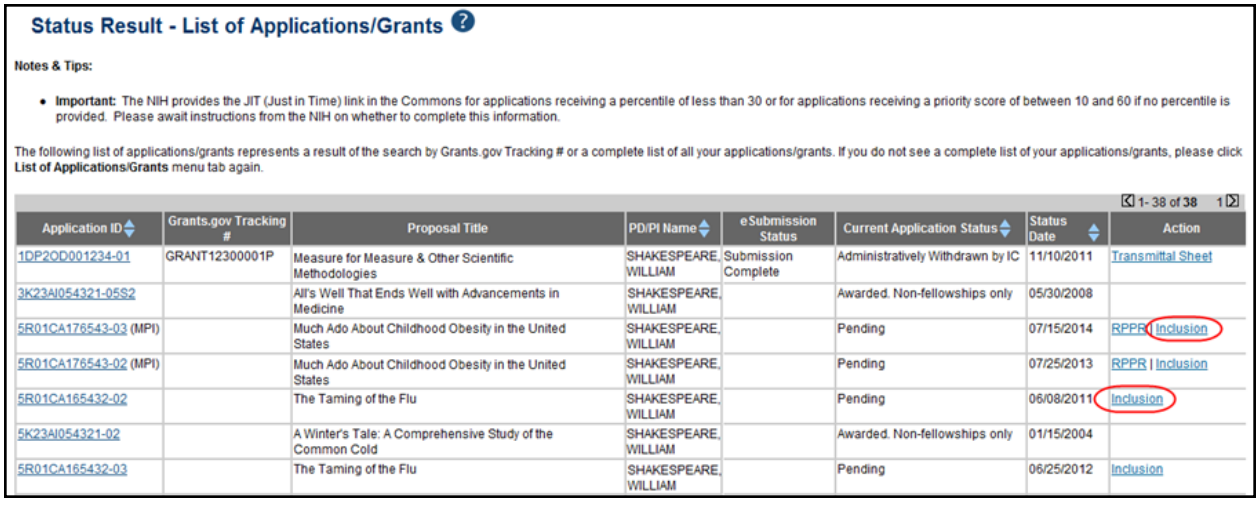
NOTE: Access to IMS from Status may be blocked after a user in your organization makes changes to the inclusion data as part of a Research Progress Performance Report (RPPR) submission.

5.4.1 Access IMS as a PI

As a PI (or delegate), you use the *Status Result – List of Applications/Grants* screen to access IMS.

To access IMS via the Status Result:

1. Locate the correct application in the results table.
2. Select the **Inclusion** link from the **Action** column for the specific application.



Status Result - List of Applications/Grants

Notes & Tips:

- **Important:** The NIH provides the JIT (Just in Time) link in the Commons for applications receiving a percentile of less than 30 or for applications receiving a priority score of between 10 and 60 if no percentile is provided. Please await instructions from the NIH on whether to complete this information.

The following list of applications/grants represents a result of the search by Grants.gov Tracking # or a complete list of all your applications/grants. If you do not see a complete list of your applications/grants, please click **List of Applications/Grants** menu tab again.

1- 38 of 38 1

Application ID	Grants.gov Tracking #	Proposal Title	PD/PI Name	eSubmission Status	Current Application Status	Status Date	Action
1DP2OD001234-01	GRANT12300001P	Measure for Measure & Other Scientific Methodologies	SHAKESPEARE, WILLIAM	Submission Complete	Administratively Withdrawn by IC	11/10/2011	Transmittal Sheet
3K23AI054321-05S2		All's Well That Ends Well with Advancements in Medicine	SHAKESPEARE, WILLIAM		Awarded. Non-fellowships only	05/30/2008	
5R01CA176543-03 (MPI)		Much Ado About Childhood Obesity in the United States	SHAKESPEARE, WILLIAM		Pending	07/15/2014	RPPR | Inclusion
5R01CA176543-02 (MPI)		Much Ado About Childhood Obesity in the United States	SHAKESPEARE, WILLIAM		Pending	07/25/2013	RPPR | Inclusion
5R01CA165432-02		The Taming of the Flu	SHAKESPEARE, WILLIAM		Pending	06/08/2011	Inclusion
5K23AI054321-02		A Winter's Tale: A Comprehensive Study of the Common Cold	SHAKESPEARE, WILLIAM		Awarded. Non-fellowships only	01/15/2004	
5R01CA165432-03		The Taming of the Flu	SHAKESPEARE, WILLIAM		Pending	06/25/2012	Inclusion

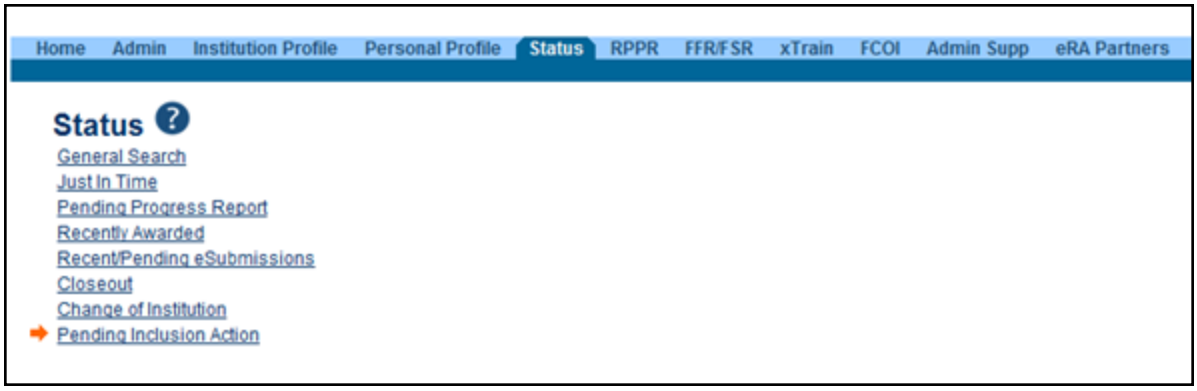
The *Inclusion–Manage Inclusion Data Records (IDRs)* screen displays any existing IDRs for the application. You will use this screen to access the features for submitting new records, viewing existing records, editing planned data, editing cumulative data, routing IDRs, and submitting IDRs (SO or authorized PIs).

IMPORTANT: IMS blocks the ability to manage IDRs accessed via the Status screens if the IDRs have already been saved by yourself or another permitted grantee via the progress report (i.e., RPPR). In this event, when accessing the IDRs via Commons Status screens, you will only be able to view the information.

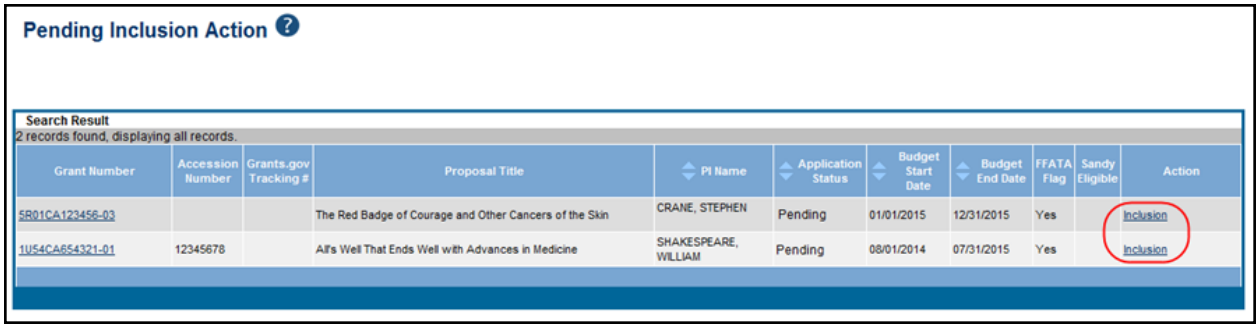
For more information on the *Inclusion–Manage Inclusion Data Records (IDRs)* screen and available actions within, refer to the topic titled *Inclusion - Manage Inclusion Data Records* on Page xviii.

5.4.2 Access IMS as an SO

As a Signing Official (SO), you can retrieve and view a list of applications having Inclusion Data Records (IDRs) that require updates or another action. Selecting the **Pending Inclusion Action** link from the main Status page prompts Commons to display grants for which the IDR(s) are in a status of *Grantee Updates in Progress* or *Pending SO*.



To view or manage these IDRs, select the **Inclusion** link from the records on the screen. After selecting the link, you will be taken to the *Inclusion–Manage Inclusion Data Records (IDRs)* screen on which IDRs for the application are displayed.



This *Pending Inclusion Action* feature in Status provides a quick means viewing only grants with inclusion needs. However, if you perform a specific search using the *Status Results–General*

Search screen will find the **Inclusion** link there, in the **Action** column, if inclusion monitoring is required for the grant.

5 Inclusion - Manage Inclusion Data Records

Grantees use the *Inclusion–Manage Inclusion Data Records (IDRs)* screen to begin the process of submitting new planned enrollment records or to view a list of all IDRs for a given grant application and to manage those individual records where applicable.

The top portion of the screen displays the Grant number, the PI Name, and the SO selected for inclusion-related email notification (if selected). Refer to the topic titled *Select SO for Inclusion Emails* on Page xliii.

When inclusion data records exist, they display in the hitlist, which displays inclusion record details and links for viewing or editing IDRs as appropriate. The information is displayed by project number in a table. IDRs on the subproject level submitted through the Application Submission System and Interface for Submission Tracking (ASSIST) are displayed on the parent level though they may be associated with a particular subproject.

Some IDRs represent studies in the current funding period for which existing datasets or resources were used to conduct the study (with no planned enrollment) or are from the progress report provided with the most recent competing renewal submission. If IDRs exist matching these criteria, they will display with only the **View** action link and a message on the top of the screen will indicate the reason (e.g., *The application has been awarded, and IDRs cannot be created or edit for that fiscal year.*)

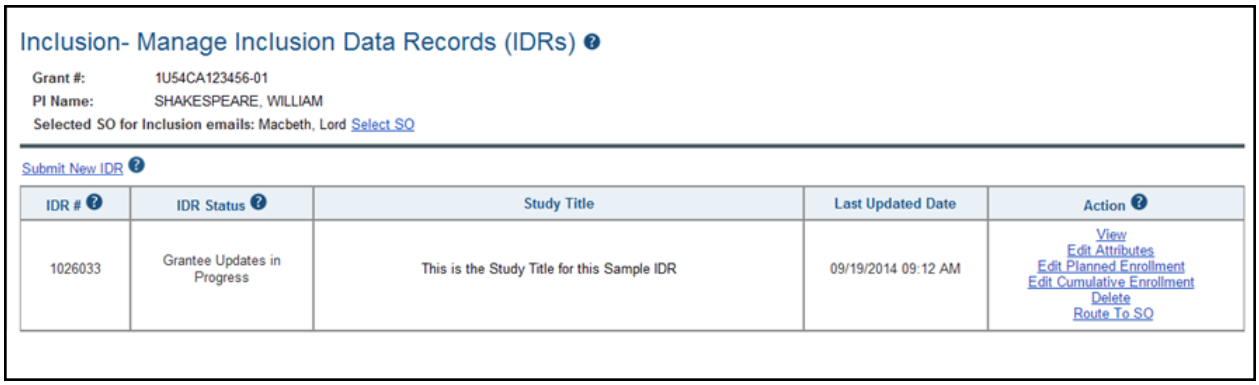
NOTE: The **Submit New IDR** link is the only option you will see when inclusion monitoring is required and no IDRs exist. Select the link to open the *Edit IDR Attributes* screen to begin the process of submitting a new report. Refer to the topic titled *Edit Inclusion Data Record (IDR) Attributes* on Page xxiii for more information.

The information provided in the hitlist(s) will vary depending on whether the viewed records are for a single project (or parent) or multi-year funded award.

- Single-project awards and parent applications to multi-project awards: The hitlist displays all IDRs for the application. These IDRs are editable in Commons Status before award, until accessed via RPPR. After submission of the progress report, these IDRs are available for editing via Commons Status again until the award is issued.

- Multi-year funded award: The hitlist displays all IDRs for the award, grouped by fiscal year with the current fiscal year displayed at the top of the list. The IDRs for previous fiscal years display below the current year and can only be viewed. Only IDRs for the current fiscal year are editable. These IDRs are locked once the each budget start date anniversary is passed.

Click here to display sample images.

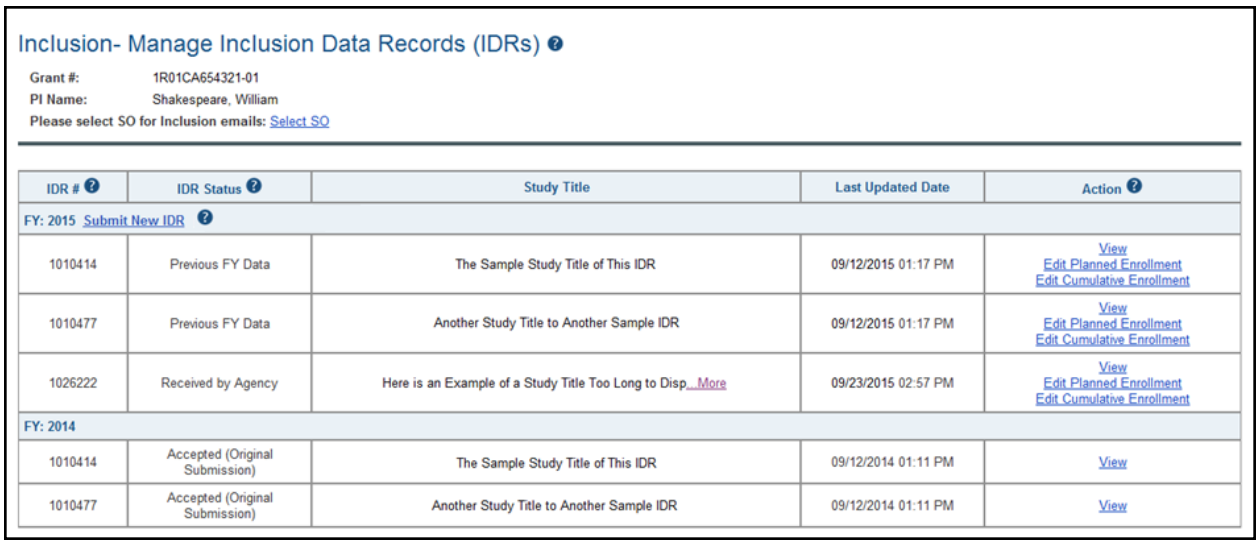


Inclusion- Manage Inclusion Data Records (IDRs)

Grant #: 1U54CA123456-01
PI Name: SHAKESPEARE, WILLIAM
Selected SO for Inclusion emails: Macbeth, Lord Select SO

Submit New IDR

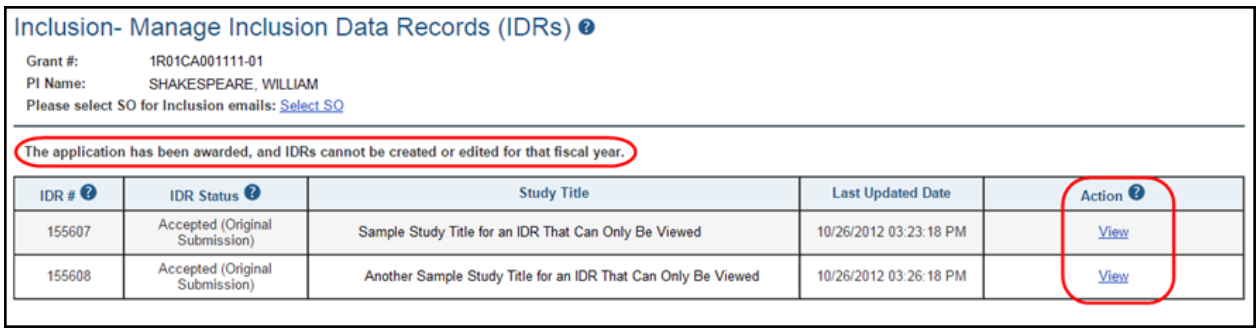
IDR #	IDR Status	Study Title	Last Updated Date	Action
1026033	Grantee Updates in Progress	This is the Study Title for this Sample IDR	09/19/2014 09:12 AM	View Edit Attributes Edit Planned Enrollment Edit Cumulative Enrollment Delete Route To SO



Inclusion- Manage Inclusion Data Records (IDRs)

Grant #: 1R01CA654321-01
PI Name: Shakespeare, William
Please select SO for Inclusion emails: Select SO

IDR #	IDR Status	Study Title	Last Updated Date	Action
FY: 2015 Submit New IDR				
1010414	Previous FY Data	The Sample Study Title of This IDR	09/12/2015 01:17 PM	View Edit Planned Enrollment Edit Cumulative Enrollment
1010477	Previous FY Data	Another Study Title to Another Sample IDR	09/12/2015 01:17 PM	View Edit Planned Enrollment Edit Cumulative Enrollment
1026222	Received by Agency	Here is an Example of a Study Title Too Long to Disp...More	09/23/2015 02:57 PM	View Edit Planned Enrollment Edit Cumulative Enrollment
FY: 2014				
1010414	Accepted (Original Submission)	The Sample Study Title of This IDR	09/12/2014 01:11 PM	View
1010477	Accepted (Original Submission)	Another Study Title to Another Sample IDR	09/12/2014 01:11 PM	View



Inclusion- Manage Inclusion Data Records (IDRs)

Grant #: 1R01CA001111-01
PI Name: SHAKESPEARE, WILLIAM
Please select SO for Inclusion emails: Select SO

The application has been awarded, and IDRs cannot be created or edited for that fiscal year.

IDR #	IDR Status	Study Title	Last Updated Date	Action
155607	Accepted (Original Submission)	Sample Study Title for an IDR That Can Only Be Viewed	10/26/2012 03:23:18 PM	View
155608	Accepted (Original Submission)	Another Sample Study Title for an IDR That Can Only Be Viewed	10/26/2012 03:26:18 PM	View

The information provided in the hitlists is as follows:

- **IDR#**

  The word *Final* appears after the IDR number to indicate that the IDR was created in the Last Support Year and is designated as a *Final IDR*.

- **IDR Status**

  Refer to the topic titled *Inclusion Data Record Statuses* on Page xlix for a list and definition of all available statuses.

- **Study Title**
- **Last Updated Date**
- **Action**

Use the links in the **Action** column to perform specific actions against the IDR. Depending on the award type, IDR status, and/or IMS system user's role, the following action links may be available from the *Inclusion–Manage Inclusion Data Records (IDRs)* **Action** column. Not all links are available to all users or for all inclusion records.

Possible actions include the following:

View

Select the **View** link to open a read-only view of the *Inclusion Data Record (IDR) Details* screen. For more information on this screen, refer to the topic titled *Inclusion Data Record Details* on Page xxx.

The **View** link is available for all IDRs, but is the only available option for the following IDRs:

- IDRs for a single-project and multi-project for which inclusion data was accessed via the RPPR
- IDRs for awarded single-project and multi-project
- IDRs for past years of a multi-year funded award
- IDRs with only cumulative enrollment data

Edit Attributes

Select the **Edit Attributes** link to access the *Edit Inclusion Data Record (IDR)* screen for editing or viewing an IDR's attributes. Refer to the topic titled *Edit Inclusion Data Record (IDR) Attributes* on Page xxiii for more information.

IMPORTANT: This link is not available if the IDR is marked as Not Funded or Type 2 Progress Report.

Edit Planned Enrollment

Select the **Edit Planned Enrollment** link to access the *Edit Enrollment Counts* screen for editing existing planned enrollment data. Refer to the topic titled *Edit Enrollment Counts* on Page xxv for more information.

The **Edit Planned Enrollment** link appears for single- and multi-project awards at all times before award. For multi-year awards, the link is available only for the current year of the IDR.

This link may also appear for Final IDRs. Refer to the topic titled Refer to *Last Support Year* for more details.

IMPORTANT: This link is not available if the IDR is marked as Delayed Onset Study, Not Funded, or Type 2 Progress Report.

Edit Cumulative Enrollment

Select the **Edit Cumulative Enrollment** link to access the *Edit Enrollment Counts* screen for editing cumulative enrollment data. Refer to the topic titled *Edit Enrollment Counts* on Page xxv for more information.

The **Edit Cumulative Enrollment** link appears for single- and multi-project awards at all times before award. For multi-year awards, the link is available only for the current year of the IDR.

IMPORTANT: This link is not available if the IDR is marked as Delayed Onset Study, Not Funded, or Type 2 Progress Report.

Delete

IDRs that were created by a Grantee via Commons Status or RPPR and never submitted to the Agency can be deleted. Use the **Delete** link to delete these inclusion records. When the link is selected, a confirmation message displays: *Are you sure you want to delete this Inclusion Data Record? You will lose all related enrollment data. Do you want to Continue?*

From this confirmation, select the **Continue** button to complete the process or the **Cancel** button to abort the deletion. Once confirmed, this action cannot be undone.

Route to SO

PIs, PI delegates, and AOs use the **Route to SO** link to send the IDR to a Signing Official for review or submission. Refer to the topic titled *Route to SO* on Page xlii for more information.

Return to PI

SOs use the **Return to PI** link to send a routed IDR back to the PI. Refer to the topic titled *Return to PI* on Page xliv for more information.

Route to Agency

SOs and PIs delegated with submit authority by the SO use the **Route to Agency** link to submit the

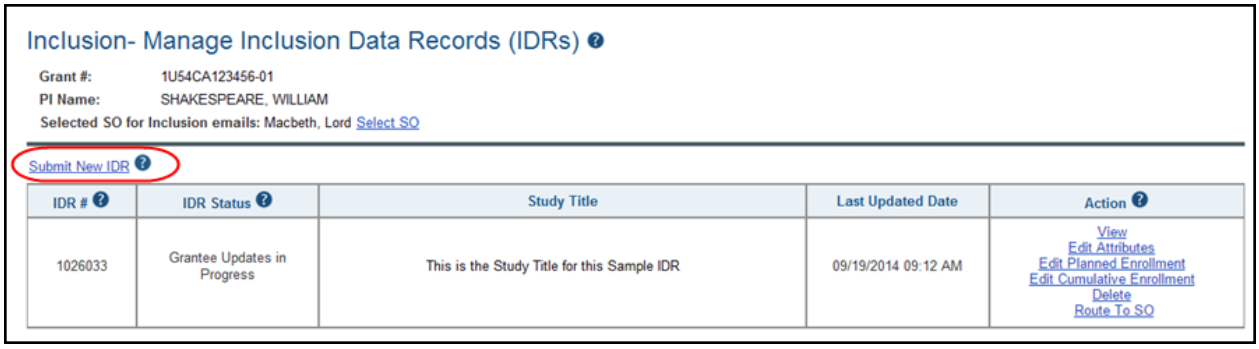
IDR to the awarding agency. Refer to the topic titled *Route to Agency* on Page xlv for more information.

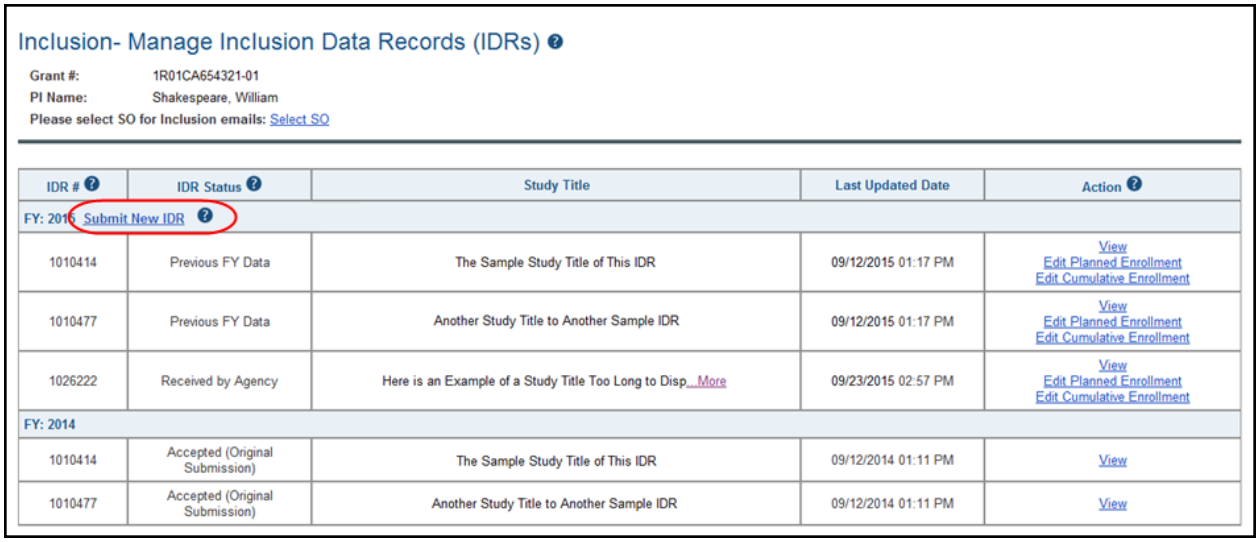
5.5 Submit New IDR

PIs can create new IDRs for single- and multi-project awards and for the current year of multi-year awards until the progress report has been submitted and the award issued (or the budget start date anniversary has passed for a multi-year funded award). It may be necessary to submit a new Inclusion Data Record (or update an existing IDR set to Delayed Onset = yes) if a grantee has studies that were not designed prior to competing submission and now are ready to start.

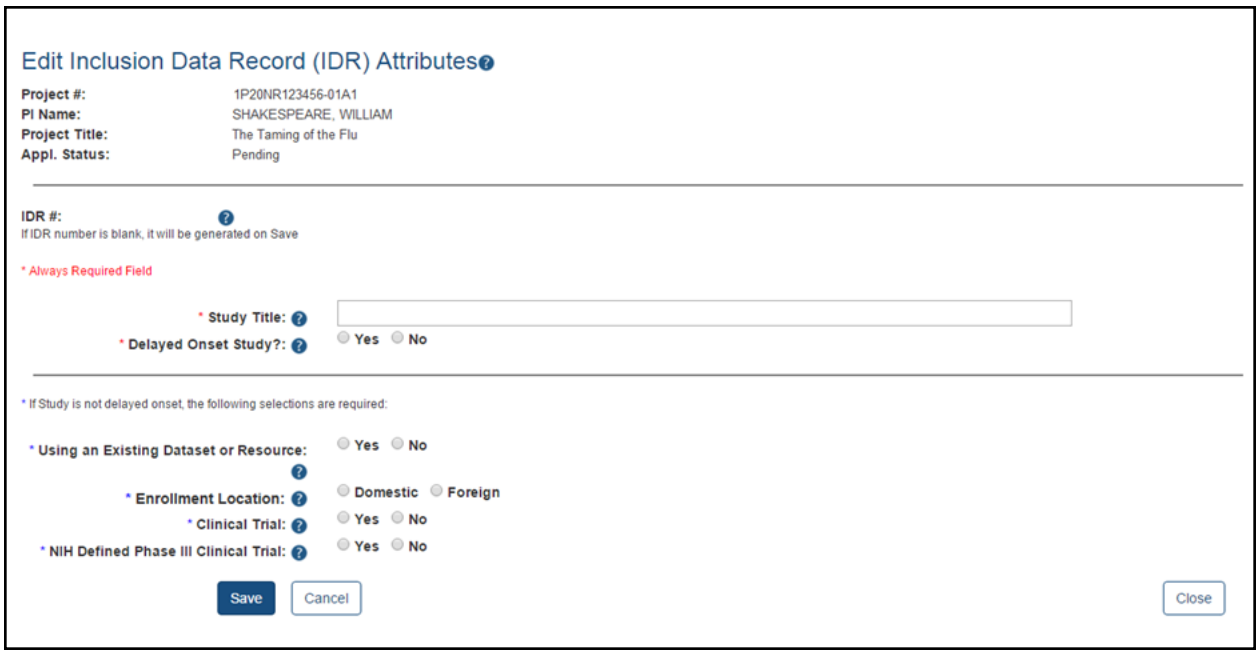
PIs can also submit new planned data for study commencing during the period of time between award of the last non-competing support year and the end of the project period. These IDRs are called Final IDRs. Refer to the topic titled *Last Support Year* for more information.

To submit new IDRs, select the **Submit New IDR** link on the *Inclusion–Manage Inclusion Data Records (IDRs)* screen.





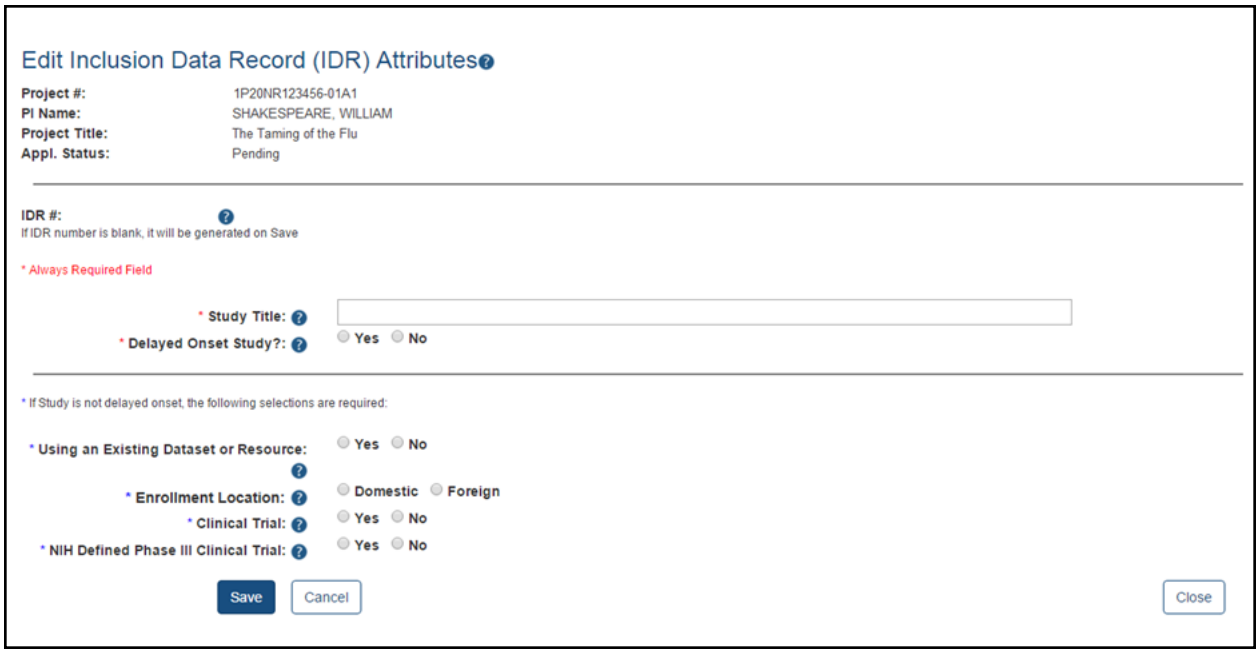
This link opens the *Edit Inclusion Data Records (IDR) Attributes* screen. To create an IDR, you must first create the attributes for that IDR. For details on this screen, refer to the topic titled *Edit Inclusion Data Record (IDR) Attributes* on Page xxiii.



Edit Inclusion Data Record (IDR) Attributes Screen

5.6 Edit Inclusion Data Record (IDR) Attributes

Use the *Edit Inclusion Data Record (IDR) Attributes* screen, shown here, to set an IDR's attributes while creating the IDR or to edit the attributes of an existing IDR.



You launch this screen from the *Inclusion – Manage Inclusion Data Records* screen by clicking the **Submit New IDR** link to create a new IDR, or the **Edit Attributes** link to edit an existing IDR. For more information, see *Inclusion - Manage Inclusion Data Records* on Page xviii.

5.6.1 Working in this screen

When you create a new IDR, all attribute fields are editable. When you edit an existing attributes, the screen displays all previously populated settings.

All attributes are required unless the IDR uses a delayed onset study. If the **Delayed Onset Study** attribute is set to **Yes**, the remaining attributes – other than **Study Title**– become disabled. **Study Title** is always a required attribute.

When you click **Save**, IMS creates the IDR with the appropriate record type (Regular vs. Final), assigns an IDR ID number, and sets the status to Grantee Updates in Progress. IMS also captures the name of the person who created the IDR and the date/time.

For multiproject applications, the IDR is assigned to the parent application.

After you click **Save**, IMS returns you to the *Inclusion - Manage Inclusion Data Records* on Page xviii screen where you can edit the planned enrollment data and perform other functions. For more information on editing enrollment data, see Edit Enrollment Counts.

5.6.1.1 Guidelines for Editing IDRs

NOTE: Editing IDR attributes may be blocked after a user in your organization makes changes to the inclusion data as part of a Research Progress Performance Report (RPPR) submission.

NOTE: When editing existing attributes, you cannot change the **Delayed Onset Study** attribute from **No** to **Yes**. And if you change **Delayed Onset Study** from **Yes** to **No**, the remaining attributes become enabled and required.

Editing eSubmission IDRs

The PI can edit IDR forms submitted through eSubmission when only cumulative enrollment data is provided.

The following conditions apply:

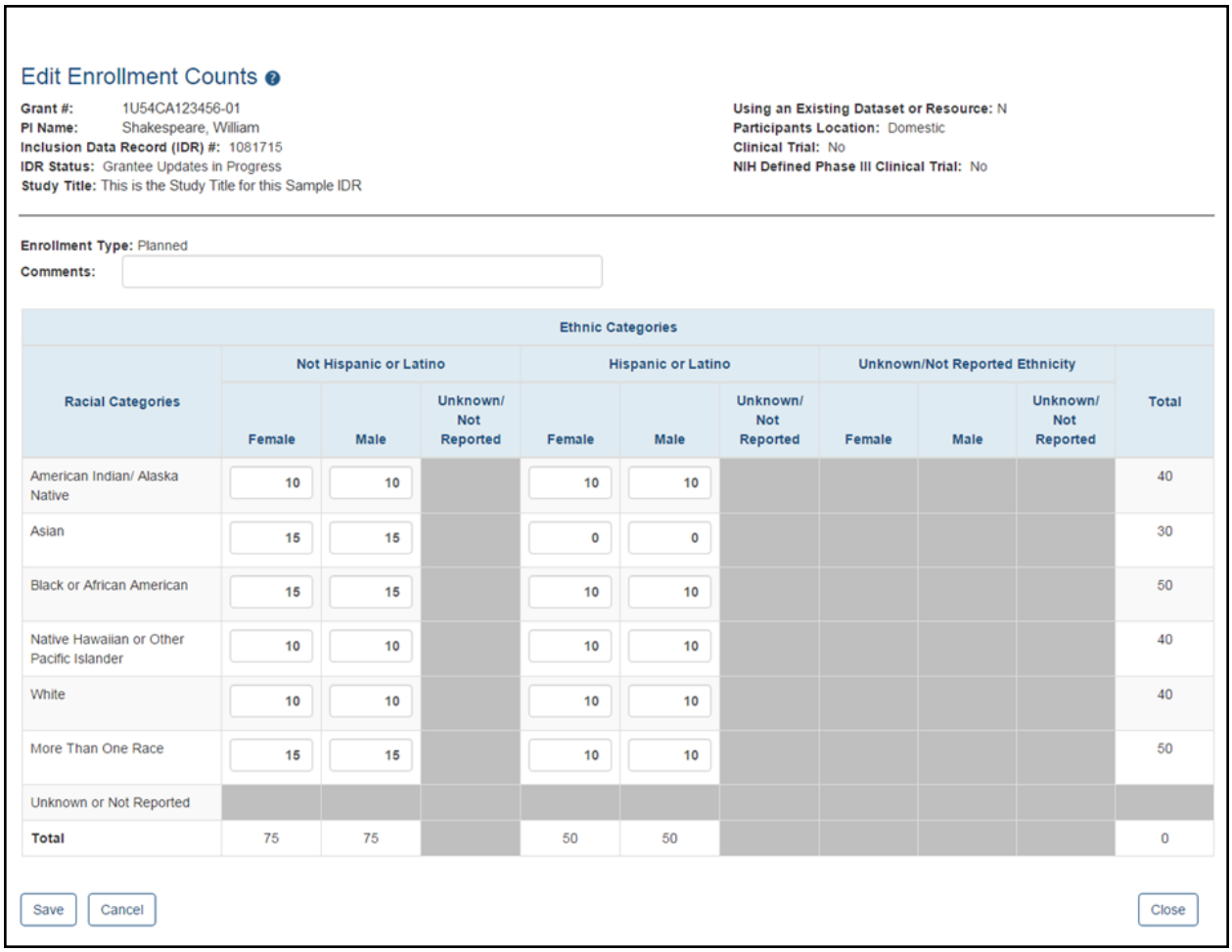
- For competing applications, the PI can edit IDR forms only if a Summary Statement exists and the application has not been awarded.
- For non-competing and merit applications, the PI can edit IDR forms as long as if the application is in one of these statuses: Pending Award (07), To be paid (35), or NRFC.

5.7 Edit Enrollment Counts

Use the *Edit Enrollment Counts* screen to edit planned or actual enrollment data for an IDR. The screen is accessed from the *Manage Inclusion Data Records* screen by selecting either the **Edit Planned Enrollment** link for editing planned enrollment counts or the **Edit Cumulative Enrollment** link for updating cumulative enrollment counts.

Refer to the topic titled *Manage Inclusion Data Records* for more information.

The *Edit Enrollment Counts* screen is similar for both planned counts and cumulative counts. Any differences are described below.



Edit Enrollment Counts

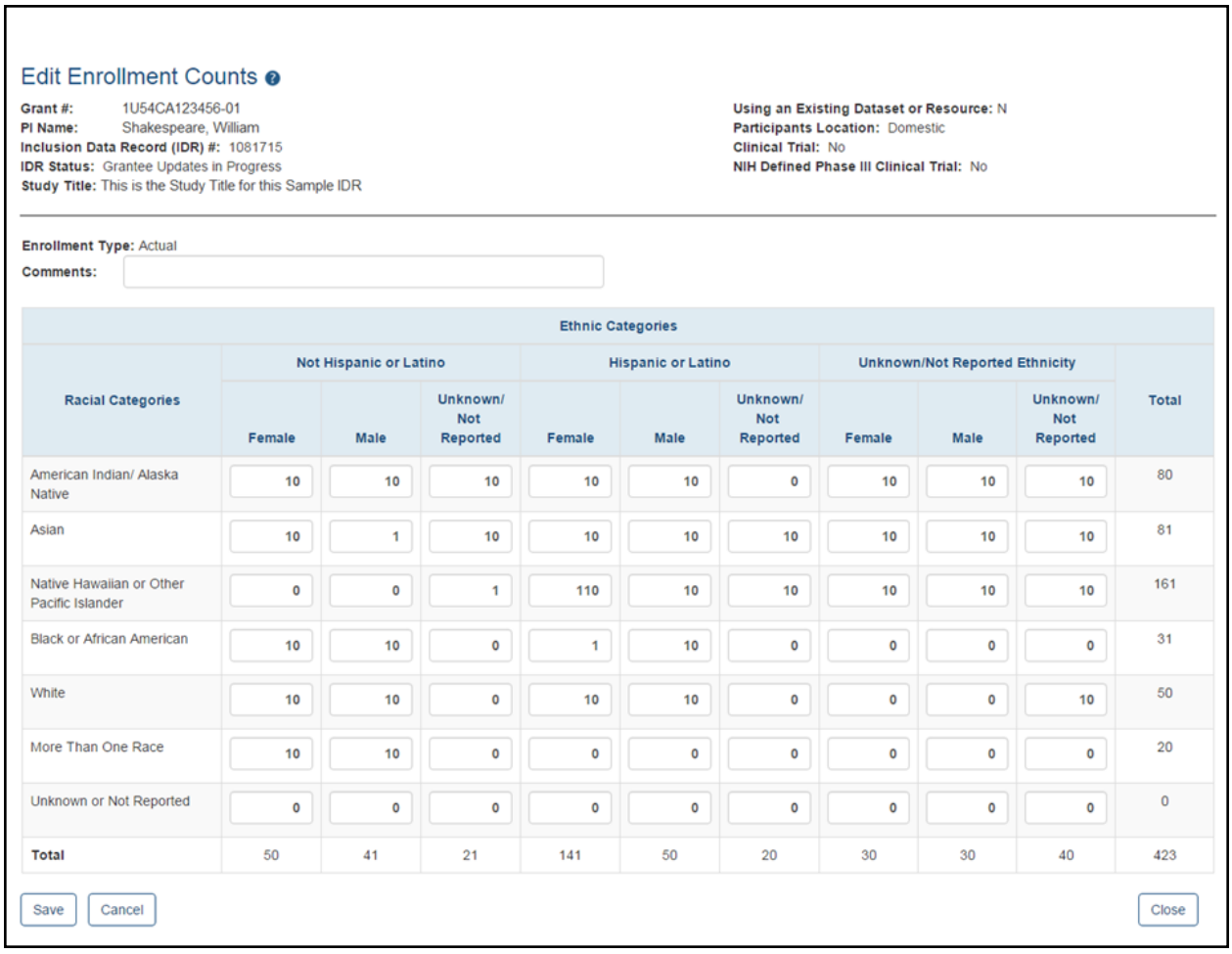
Grant #: 1U54CA123456-01
PI Name: Shakespeare, William
Inclusion Data Record (IDR) #: 1081715
IDR Status: Grantee Updates in Progress
Study Title: This is the Study Title for this Sample IDR

Using an Existing Dataset or Resource: N
Participants Location: Domestic
Clinical Trial: No
NIH Defined Phase III Clinical Trial: No

Enrollment Type: Planned
Comments:

Racial Categories	Ethnic Categories: Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			Total
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	10	10		10	10					40
Asian	15	15		0	0					30
Black or African American	15	15		10	10					50
Native Hawaiian or Other Pacific Islander	10	10		10	10					40
White	10	10		10	10					40
More Than One Race	15	15		10	10					50
Unknown or Not Reported										
Total	75	75		50	50					0

Save Cancel Close



Edit Enrollment Counts

Grant #: 1U54CA123456-01
PI Name: Shakespeare, William
Inclusion Data Record (IDR) #: 1081715
IDR Status: Grantee Updates in Progress
Study Title: This is the Study Title for this Sample IDR

Using an Existing Dataset or Resource: N
Participants Location: Domestic
Clinical Trial: No
NIH Defined Phase III Clinical Trial: No

Enrollment Type: Actual
Comments:

Racial Categories	Ethnic Categories: Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			Total
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	10	10	10	10	10	0	10	10	10	80
Asian	10	1	10	10	10	10	10	10	10	81
Native Hawaiian or Other Pacific Islander	0	0	1	110	10	10	10	10	10	161
Black or African American	10	10	0	1	10	0	0	0	0	31
White	10	10	0	10	10	0	0	0	10	50
More Than One Race	10	10	0	0	0	0	0	0	0	20
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	50	41	21	141	50	20	30	30	40	423

Save Cancel Close

The *Edit Enrollment Count* screen contains the following information:

Grant #

The grant to which the IDR belongs.

PI Name

The name of the contact PI on the project record.

Inclusion Data Record (IDR) #

Displays the system-generated identification number of the inclusion data record.

The words *(Last Budget Period)* appear after the IDR number to indicate that the IDR was created in the Last Budget Period IDR and is designated as a *Last Budget Period IDR*.

IDR Status

Shows the status of the record.

Study Title

The study title of the IDR, pre-populated with the existing title.

Enrollment Location

Enrollment Location indicates whether the IDR involves participants from a non-US site (i.e., foreign) or a US site (i.e., domestic).

ESelect one of these values from the drop-down menu:

- **Domestic**
- **Foreign**

Using an Existing Data Study

If there are questions regarding the definition of an existing dataset or resource, please refer to the following FAQ: http://grants.nih.gov/grants/funding/women_min/datasets_faq.htm

Existing Dataset values include:

- **Yes**
- **No**

Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

For more information, refer to the NIH glossary entry for Clinical Trial.

NIH Defined Phase III Clinical Trial

This field indicates whether the IDR is included in a study that is part of a NIH-defined Phase III Clinical Trial.

Y - indicates an NIH-defined phase III clinical trial

N - indicates clinical research, not an NIH-defined phase III clinical trial

Enrollment Type

Displays either *Planned* or *Cumulative* as appropriate.

Comments

An optional text field for entering comments for the specific enrollment type (planned or cumulative). If any comments were entered before, this field is pre-populated when editing an existing IDR. If editing existing Planned Enrollment, you should first discuss with the Program Officer and may want to consider adding a comment here to explain the change.

The enrollment form includes racial categories along the left side the of the table and ethnic categories, divided by sex/gender, along the top of the table. The individual enrollment count cells are editable and set to zero by default, when populating a new IDR. When editing an existing form, these values are pre-populated with any other values previously entered. The total fields are calculated by IMS and sum up as rows and columns accordingly. The total values are not editable fields.

IMPORTANT: The display of cumulative enrollment counts data includes fields for entering Unknown/Not Reported race, ethnicity, and sex/gender data. These fields are disabled when planned enrollment counts are displayed.

Update the values in the individual enrollment count cells as necessary, and select the **Save** button. To leave the form without saving any changes, select the **Cancel** button instead. Saving and canceling both return you to the *Inclusion–Manage Inclusion Data Records* screen.

POLICY: For additional information on racial and ethnic categories or inclusion policy, refer to the PHS Supplemental Instructions for Human Subjects or the OER inclusion web page.

IMS will perform validations to make sure the data can be saved and events may occur while editing the counts which prevent you from saving your information. Pay attention to the warnings or errors on the screen.

5.8 Last Support Year IDRs

Upon Award of the last support year, the status of a regular IDR will be changed to "Accepted" and the system will create a copy of the enrollment data (Planned and Actual) to create a **Final** type of IDR. This *Final IDR* will have the same IDR number as the regular IDR.

External and Internal users can update or create a new Final type of IDR. The status of these IDRs will be set to "*Previous data*".

Both External and Internal users can create/edit a *Final IDR* until the Grant is closed. These *Final IDR*s will be marked as "(*Final*)" next to the IDR number.

The routing for a *Final IDR* will be the same as a regular type of IDR.

When a *Final RPPR* is initiated External users will only have the ability to edit *Final IDR*s and can only create a *Final IDR*."

Previous regular IDRs will be viewable.

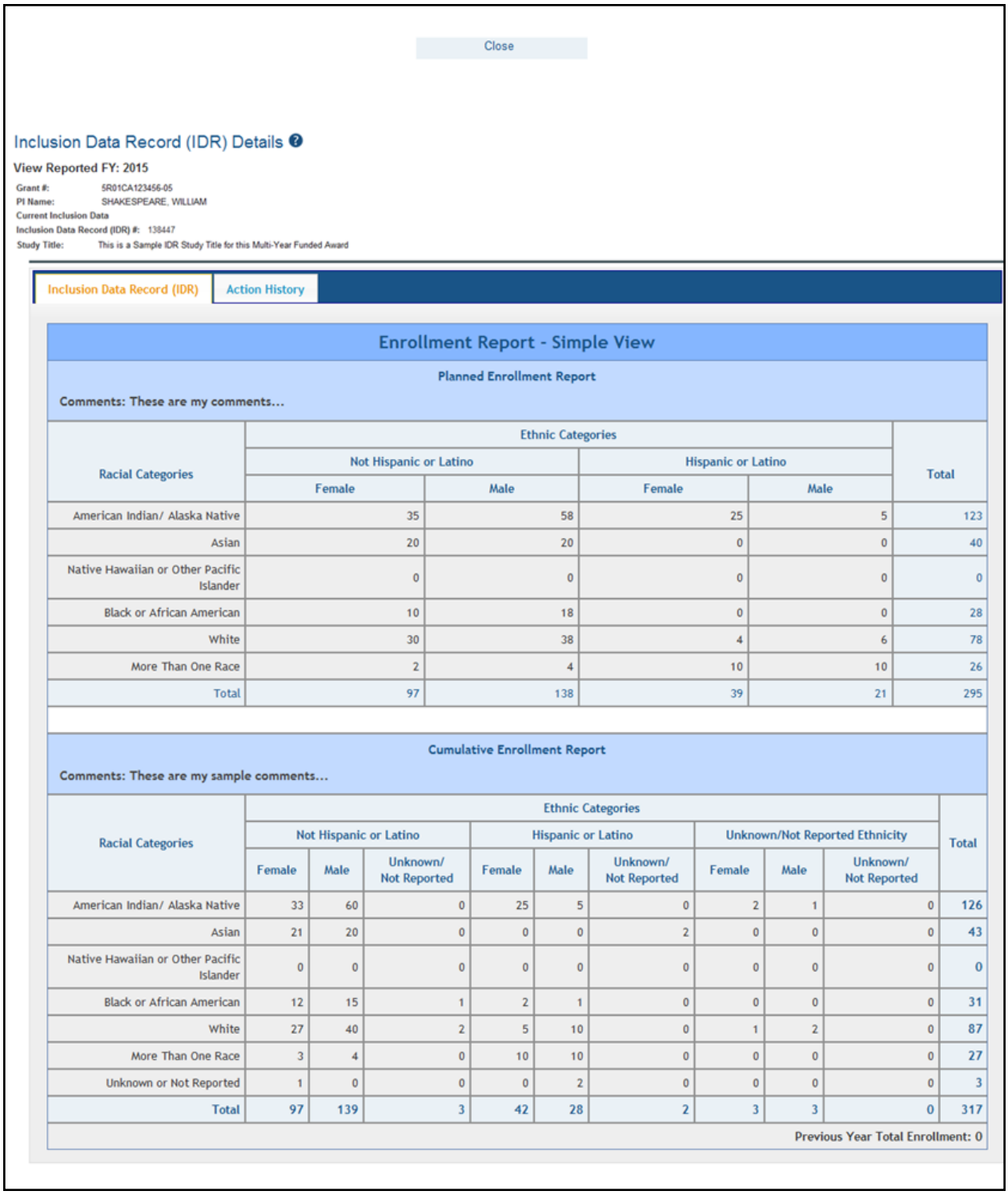
5 Inclusion Data Record Details

Access the *Inclusion Data Record (IDR) Details* screen by selecting the **View** action option from the *Inclusion–Manage Inclusion Data Records (IDRs)*screen.

You can use this screen to view details of a selected IDR, including including planned and cumulative enrollment reports and history of actions performed on the IDR. The information displayed on the screen is read-only.

The screen provides the ability to switch between all fiscal years and between all existing versions of the requested IDR. Each time edits to an IDR are sent to the agency a version is created so as not to overwrite existing information. It allows you to view the *Work in Progress* IDR (for IDRs in *Grantee Updates in Progress*, *Pending SO*, *Requires Updates*, or *Inclusion Updated* status).

Click here to display a sample image.



Close

Inclusion Data Record (IDR) Details

View Reported FY: 2015

Grant #: 5R01CA123456-05
PI Name: SHAKESPEARE, WILLIAM
Current Inclusion Data
Inclusion Data Record (IDR) #: 138447
Study Title: This is a Sample IDR Study Title for this Multi-Year Funded Award

Inclusion Data Record (IDR) | Action History

Enrollment Report - Simple View

Planned Enrollment Report

Comments: These are my comments...

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	35	58	25	5	123
Asian	20	20	0	0	40
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	10	18	0	0	28
White	30	38	4	6	78
More Than One Race	2	4	10	10	26
Total	97	138	39	21	295

Cumulative Enrollment Report

Comments: These are my sample comments...

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	33	60	0	25	5	0	2	1	0	126
Asian	21	20	0	0	0	2	0	0	0	43
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	12	15	1	2	1	0	0	0	0	31
White	27	40	2	5	10	0	1	2	0	87
More Than One Race	3	4	0	10	10	0	0	0	0	27
Unknown or Not Reported	1	0	0	0	2	0	0	0	0	3
Total	97	139	3	42	28	2	3	3	0	317

Previous Year Total Enrollment: 0

The header section of the screen displays general project and IDR information. Additional IDR data is displayed on tabs within the screen.

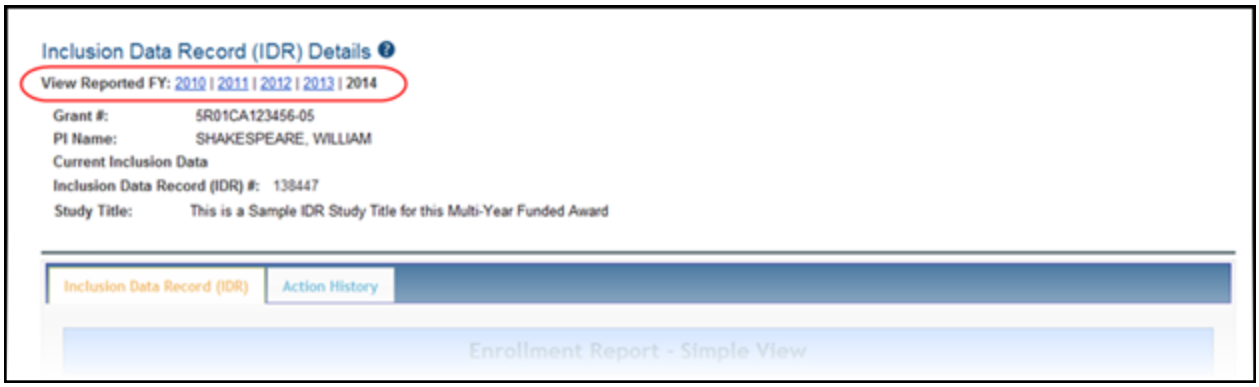
- **Inclusion Data Record (IDR)** tab
- **Action History** tab

Header Section

The header section of *Inclusion Data Record (IDR) Details* displays the appropriate information for the grant application record to which the selected IDR belongs. The following information is included in the header section of the screen:

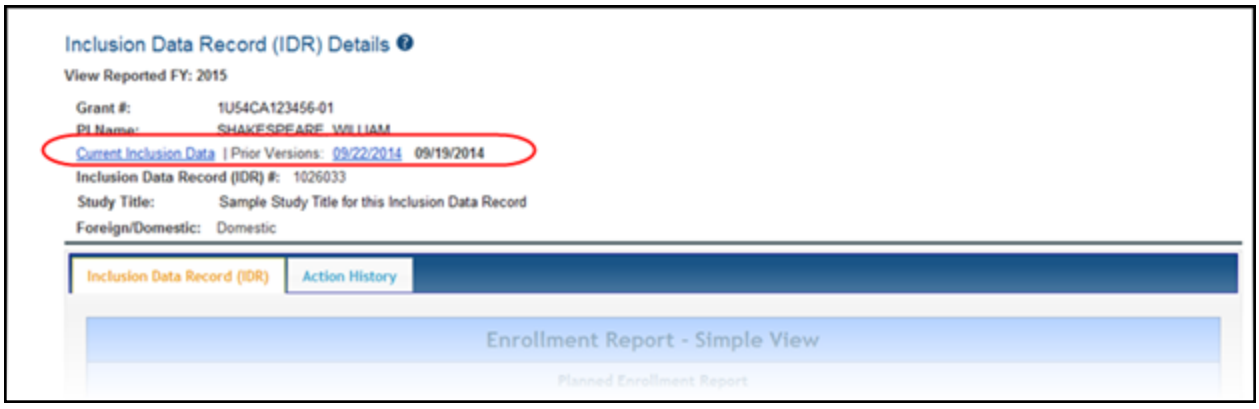
- **View Reported FY**

  IMS allows switching between fiscal years of an application/award (or fiscal year of an IDR for multi-year award) by selecting the appropriate year's link. The screen's default view depends on which record was chosen to view when you accessed the screen. When a fiscal year's IDR is in the current view, the link becomes disabled and is displayed as bold text instead.

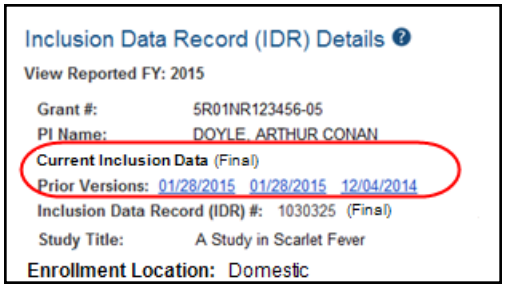


- **Grant #**
- **PI Name**
- **Current Inclusion Data|Prior Versions**

  To view prior versions of the IDR, select the date link of the prior version you wish to view. To return to the current version, select the **Current Inclusion Data** link. The corresponding link –either the current version or a selected prior version – displays in bold font as a visual indication of the view.



When viewing *Inclusion Data Record (IDR) Details* for a Final IDR, the word *Final* displays next to the **Current Inclusion Data** label. On the same line, links to the prior version of the Final IDR (if applicable) display next to the title **Prior Versions of Final IDR**. Links to the prior version(s) of the corresponding *regular* IDR display beneath this information, next to the label **Prior Versions**; these links do not exist for Final IDRs not associated with a regular IDR (i.e., new study).



- **Inclusion Data Record (IDR) #**

  The word *Final* appears after the IDR number to indicate that the IDR was created in the Last Support Year and is designated as a *Final IDR*.

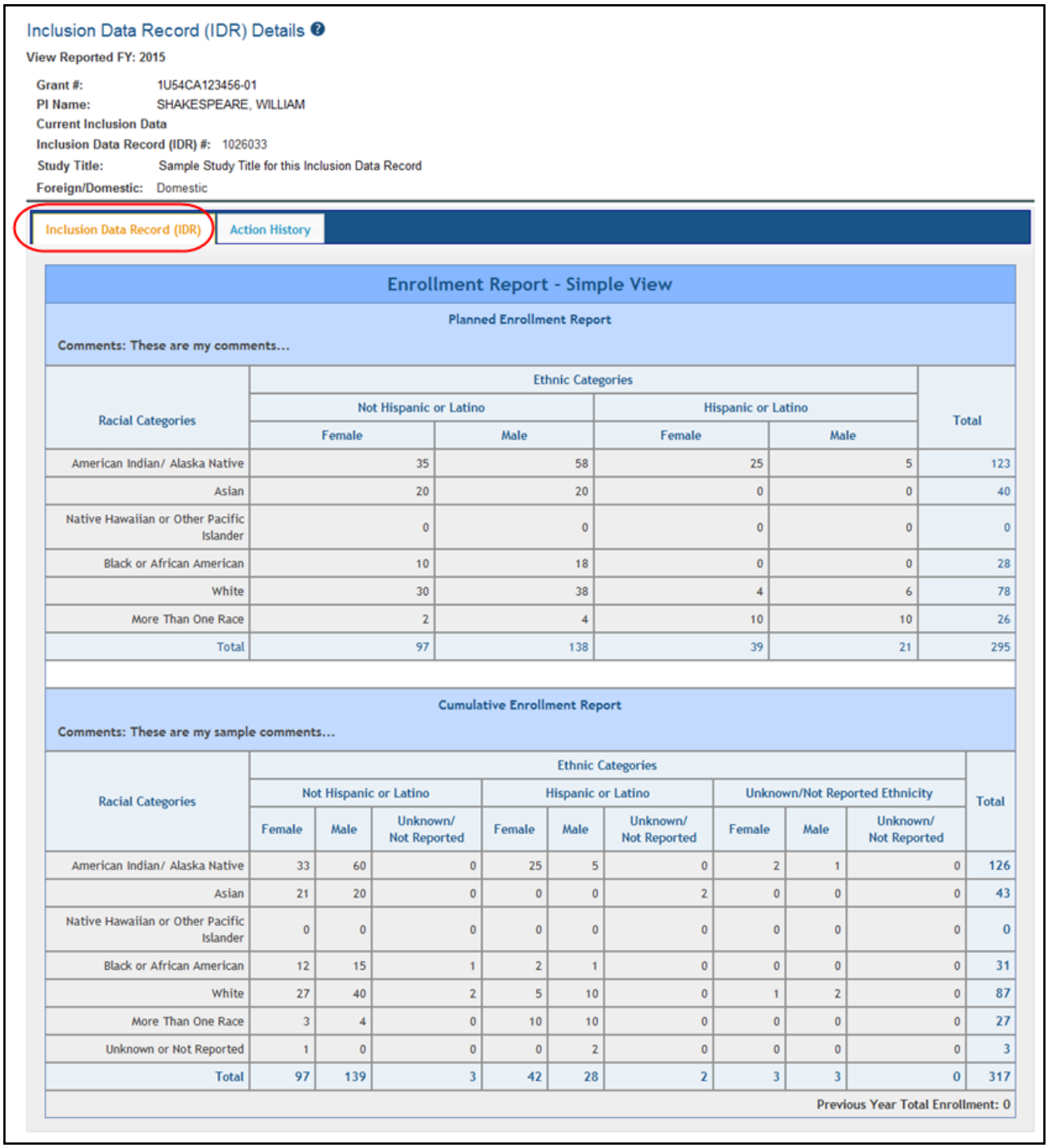
- **Study Title**
- **Foreign/Domestic** indicator

5.9 Enrollment Report – Simple View

The **Enrollment Report – Simple View** section of the *Inclusion Data Record (IDR) Details* screen shows simple tables of enrollment information for planned enrollment and cumulative

enrollment for the selected version, where available.

Click here to display a sample image.



Inclusion Data Record (IDR) Details

View Reported FY: 2015

Grant #: 1U54CA123456-01
PI Name: SHAKESPEARE, WILLIAM
Current Inclusion Data
Inclusion Data Record (IDR) #: 1026033
Study Title: Sample Study Title for this Inclusion Data Record
Foreign/Domestic: Domestic

Inclusion Data Record (IDR) | Action History

Enrollment Report - Simple View

Planned Enrollment Report

Comments: These are my comments...

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	35	58	25	5	123
Asian	20	20	0	0	40
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	10	18	0	0	28
White	30	38	4	6	78
More Than One Race	2	4	10	10	26
Total	97	138	39	21	295

Cumulative Enrollment Report

Comments: These are my sample comments...

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	33	60	0	25	5	0	2	1	0	126
Asian	21	20	0	0	0	2	0	0	0	43
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	12	15	1	2	1	0	0	0	0	31
White	27	40	2	5	10	0	1	2	0	87
More Than One Race	3	4	0	10	10	0	0	0	0	27
Unknown or Not Reported	1	0	0	0	2	0	0	0	0	3
Total	97	139	3	42	28	2	3	3	0	317

Previous Year Total Enrollment: 0

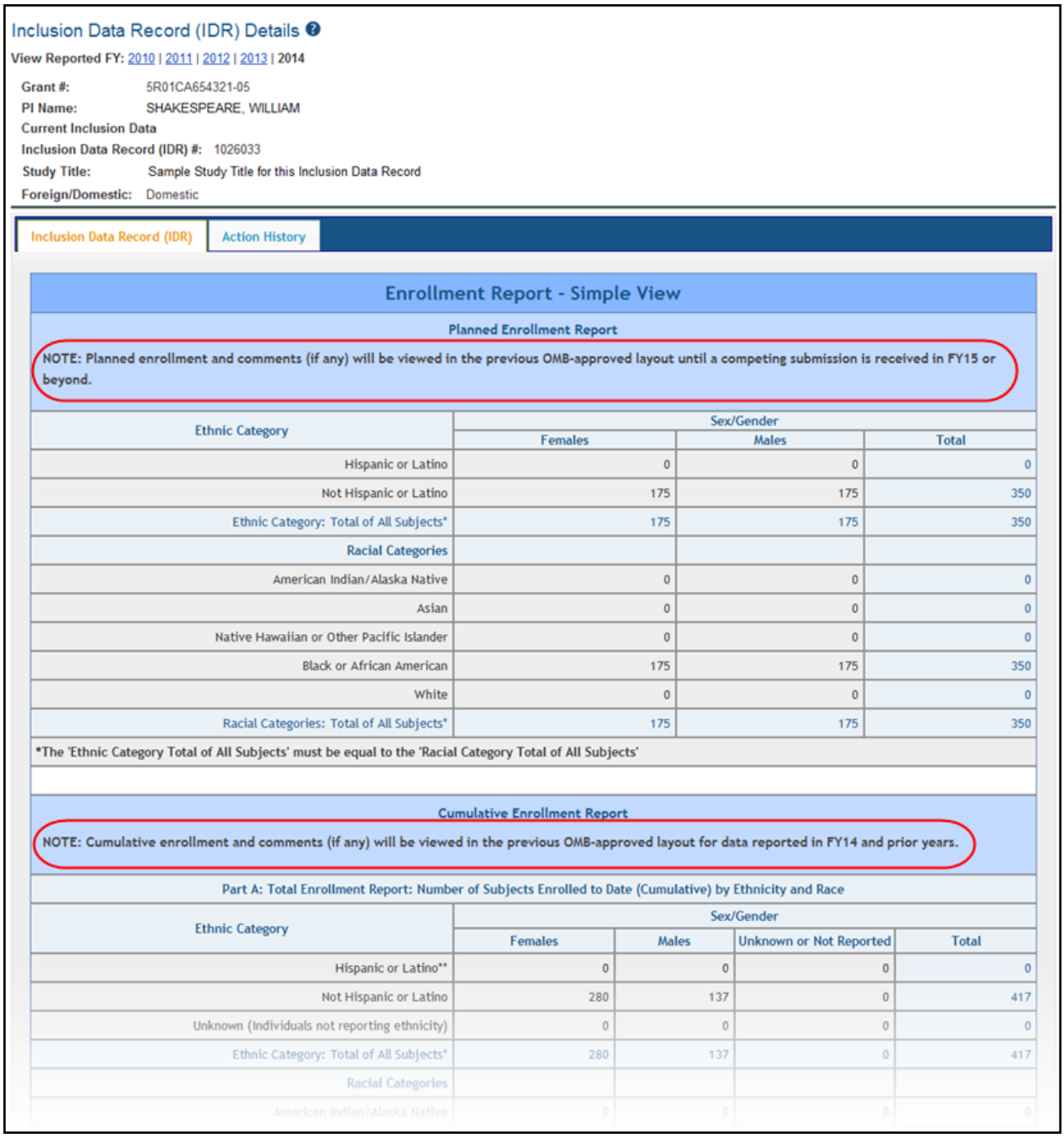
In some instances, the data is not available or is available in the previous OMB-approved format. These cases are outlined below.

Data last saved in the previous NIH inclusion data system and migrated to IMS will display in the previous OMB-approved format. In this case, the following notes will appear on the screen:

- Planned Enrollment Report: *NOTE: Planned enrollment comments (if any) will be viewed in the previous OMB-approved layout until a competing submission is received in FY15 or beyond.*
- Cumulative Enrollment Report: *NOTE: Cumulative enrollment and comments (if any) will be viewed in the previous OMB-approved layout for data reported in FY14 and prior years.*
- Migrated data with no planned enrollment: *No Planned Enrollment has been provided for this fiscal year.*
- Migrated data with no cumulative enrollment data: *No cumulative data has been provided for this fiscal year.*

For data received from eSubmission where no planned enrollment data exists, the following message will display: *Cumulative enrollment data was provided with competing application; planned enrollment was not required.*

Click here to display a sample image.



Inclusion Data Record (IDR) Details

View Reported FY: 2010 | 2011 | 2012 | 2013 | 2014

Grant #: 5R01CA654321-05
PI Name: SHAKESPEARE, WILLIAM
Current Inclusion Data
Inclusion Data Record (IDR) #: 1026033
Study Title: Sample Study Title for this Inclusion Data Record
Foreign/Domestic: Domestic

Inclusion Data Record (IDR) | Action History

Enrollment Report - Simple View

Planned Enrollment Report

NOTE: Planned enrollment and comments (if any) will be viewed in the previous OMB-approved layout until a competing submission is received in FY15 or beyond.

Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	0	0	0
Not Hispanic or Latino	175	175	350
Ethnic Category: Total of All Subjects*	175	175	350
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	175	175	350
White	0	0	0
Racial Categories: Total of All Subjects*	175	175	350

*The 'Ethnic Category Total of All Subjects' must be equal to the 'Racial Category Total of All Subjects'

Cumulative Enrollment Report

NOTE: Cumulative enrollment and comments (if any) will be viewed in the previous OMB-approved layout for data reported in FY14 and prior years.

Part A: Total Enrollment Report: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

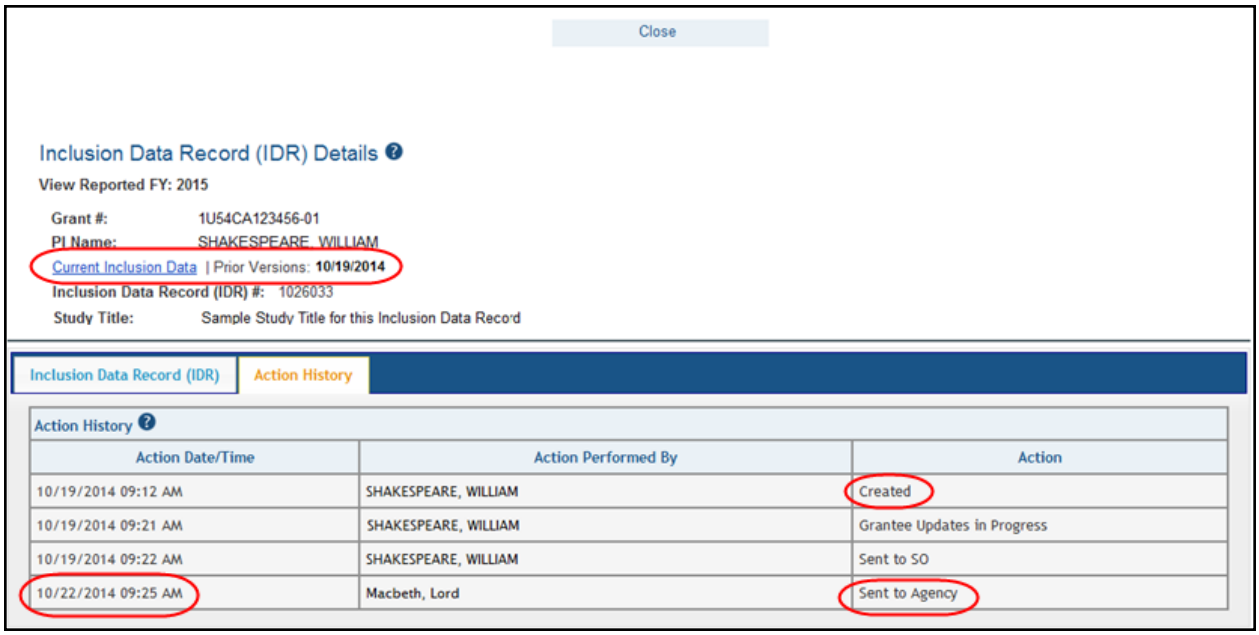
Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino**	0	0	0	0
Not Hispanic or Latino	280	137	0	417
Unknown (Individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	280	137	0	417
Racial Categories				
American Indian/Alaska Native	0	0	0	0

5.10 Action History

The **Action History** tab of the *Inclusion Data Record (IDR) Details* screen provides a list of actions performed against the IDR, including the person who performed the action.

NOTE: In the case of viewing a Last Budget Period type IDR, the screen only displays the action history of that IDR. It does not include the history of the associated regular IDR.

Click here to display a sample image.



Action History

The information is displayed in a table with the following fields:

- **Action Date/Time**

  Displays the date and time on which the action was performed in the system.

- **Action Performed By**

  Provides the name of the individual who performed the action.

- **Action**

  Displays the type of action performed against the IDR. Below is a list of possible actions and their definitions. Click the arrow next to the action to display its definition.

  - Accepted by Agency[1]
  - Copied from prior year[2]

[1]: A system-generated status update upon rollover of a multi-year funded award. The user in this event will display as System.
[2]: The IDR was created when the next budget period began.

- Created[1]
- Created Via RPPR[2]
- Created Via Web Service[3]
- Cumulative Enrollment is Updated for Progress Report[4]
- Data Locked for Reporting[5]
- Grant is Awarded[6]
- Grant is Awarded, IDR is Not Rolled Forward[7]
- Grantee Updates in Progress[8]
- Inclusion Data Accessed Via RPPR[9]
- Planned Enrollment is Updated for Progress Report[10]
- Returned to PI[11]
- Sent to Agency[12]
- Sent to Agency as Part of the Progress Report[13]
- Sent to SO[14]
- Updated by Internal Staff[13]
- Updated Via Web Service[14]

---

[1]: The IDR form (Planned or Cumulative) was received as part of the electronic application submission process, was created in the Inclusion Management System, or was migrated from POP Tracking.

[2]: The Grantee user has created the IDR by selecting the Create New IDR link after accessing the IDR via RPPR.

[3]: The IDR was inserted via web service.

[4]: The Grantee user has updated the cumulative enrollment counts after accessing the IDR via RPPR.

[5]: A system-generated status update upon freezing FY for contracts or intramural projects.

[6]: A system-generated status update upon release of the award. The user in this event will display as System.

[7]: A system-generated status update upon release of the award when the IDR is marked as *Not Funded* or *Type 2 Progress Report*. The user in this event will display as System.

[8]: The Grantee user initiated updates for the IDR by editing the planned or cumulative data.

[9]: Indicates that a Grantee user has accessed the IDR by selecting the Inclusion link from the RPPR Section G. Special Requirements.

[10]: The Grantee user has updated the planned enrollment counts after accessing the IDR via RPPR.

[11]: The SO returned a routed IDR back to the PI.

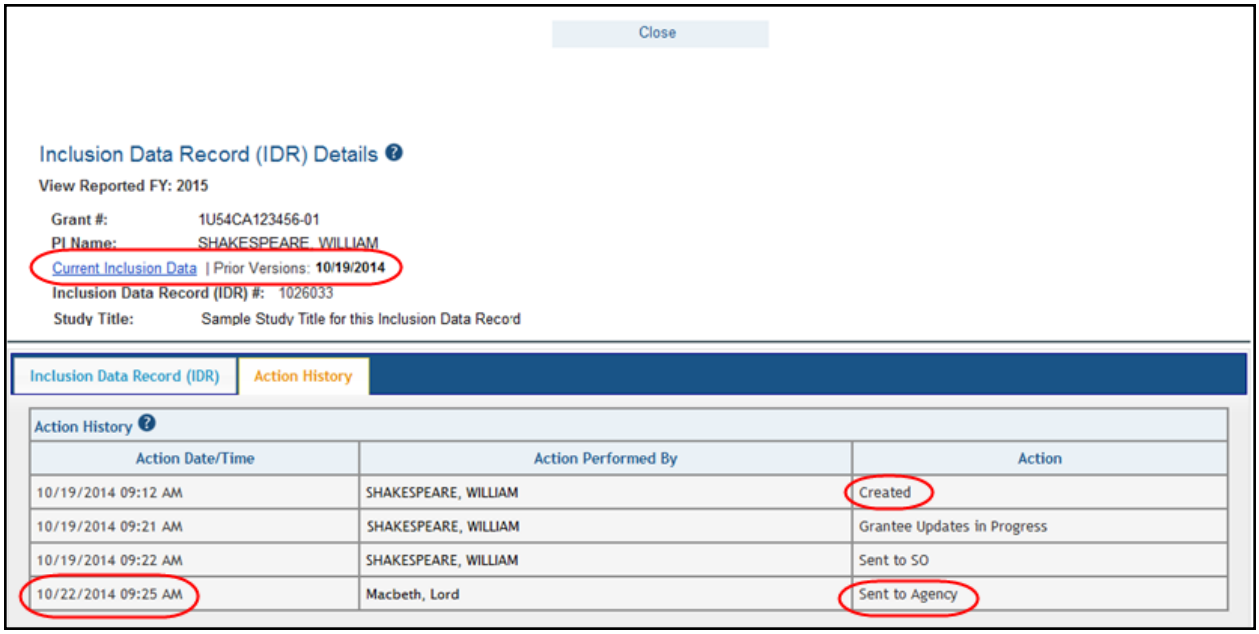
[12]: The SO (or delegate) routed the IDR to Agency.

5.11 Action History

The **Action History** tab of the *Inclusion Data Record (IDR) Details* screen provides a list of actions performed against the IDR, including the person who performed the action.

NOTE: In the case of viewing a Last Budget Period type IDR, the screen only displays the action history of that IDR. It does not include the history of the associated regular IDR.

Click here to display a sample image.



Action History

The information is displayed in a table with the following fields:

- **Action Date/Time**

  Displays the date and time on which the action was performed in the system.

- **Action Performed By**

  Provides the name of the individual who performed the action.

- **Action**

  Displays the type of action performed against the IDR. Below is a list of possible actions and their definitions. Click the arrow next to the action to display its definition.

- Accepted by Agency[1]
- Copied from prior year[2]
- Created[3]
- Created Via RPPR[4]
- Created Via Web Service[5]
- Cumulative Enrollment is Updated for Progress Report[6]
- Data Locked for Reporting[7]
- Grant is Awarded[8]
- Grant is Awarded, IDR is Not Rolled Forward[9]
- Grantee Updates in Progress[10]
- Inclusion Data Accessed Via RPPR[11]
- Planned Enrollment is Updated for Progress Report[12]
- Returned to PI[13]
- Sent to Agency[13]
- Sent to Agency as Part of the Progress Report[13]
- Sent to SO[13]

1: A system-generated status update upon rollover of a multi-year funded award. The user in this event will display as System.
2: The IDR was created when the next budget period began.
3: The IDR form (Planned or Cumulative) was received as part of the electronic application submission process, was created in the Inclusion Management System, or was migrated from POP Tracking.
4: The Grantee user has created the IDR by selecting the Create New IDR link after accessing the IDR via RPPR.
5: The IDR was inserted via web service.
6: The Grantee user has updated the cumulative enrollment counts after accessing the IDR via RPPR.
7: A system-generated status update upon freezing FY for contracts or intramural projects.
8: A system-generated status update upon release of the award. The user in this event will display as System.
9: A system-generated status update upon release of the award when the IDR is marked as *Not Funded* or *Type 2 Progress Report*. The user in this event will display as System.
10: The Grantee user initiated updates for the IDR by editing the planned or cumulative data.
11: Indicates that a Grantee user has accessed the IDR by selecting the Inclusion link from the RPPR Section G. Special Requirements.
12: The Grantee user has updated the planned enrollment counts after accessing the IDR via RPPR.

- Updated by Internal Staff[1]
- Updated Via Web Service[2]

[1]: Data on the planned or actual enrollment form was updated by agency staff.

[2]: The IDR was updated via web service.

5 Routing & Submitting IDRs

The routing feature exists in the IMS to allow grantee users (e.g., PIs, PI delegates, SOs) to send IDRs to others for review or submission. Routing refers to the processes of sending an IDR to the Signing Official (SO) for review; sending an IDR back to the PI for editing; and submitting the IDR to Agency.

Routing is performed by selecting the appropriate action link from the *Inclusion–Manage Inclusion Data Records (IDRs)* screen:

- **Route to SO**
- **Return to PI**
- **Route to Agency**

Refer to the individual routing topics for more information.

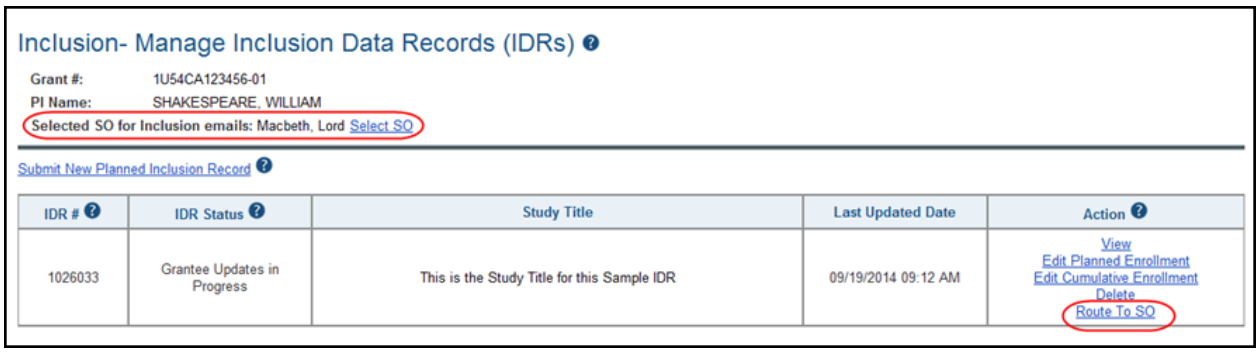
5.12 Route to SO

As the PI, you will need to route IDRs (in status of *Grantee Updates in Progress* – including Final IDRs – to a Signing Official (SO) who is responsible for submitting the IDR to the Agency. This function is performed on the *Inclusion–Manage Inclusion Data Records (IDRs)* screen.

NOTE: PIs who are granted authority in eRA Commons to submit progress reports directly may not need to perform this *Route to SO* function.

To route the IDR to an SO:

1. Navigate to the *Inclusion–Manage Inclusion Data Records (IDRs)* screen
2. Verify that an SO name appears in the **Select SO for Inclusion Emails** field. *You must first choose an SO before routing the IDR.* For information on selecting an SO, refer to the topic titled *Select SO for Inclusion Emails* on Page xliii.
3. Locate the IDR to route from the **Prospective Studies** hitlist.
4. Select the **Route to SO** link. The link will only display for IDRs in a status of *Grantee Updates in Progress*.



When routed to the SO, the following actions occur:

- Email notification is sent to the selected SO
- IDR status updates to *Pending SO*
- The action is recorded in the *Action History*

5.13 Select SO for Inclusion Emails

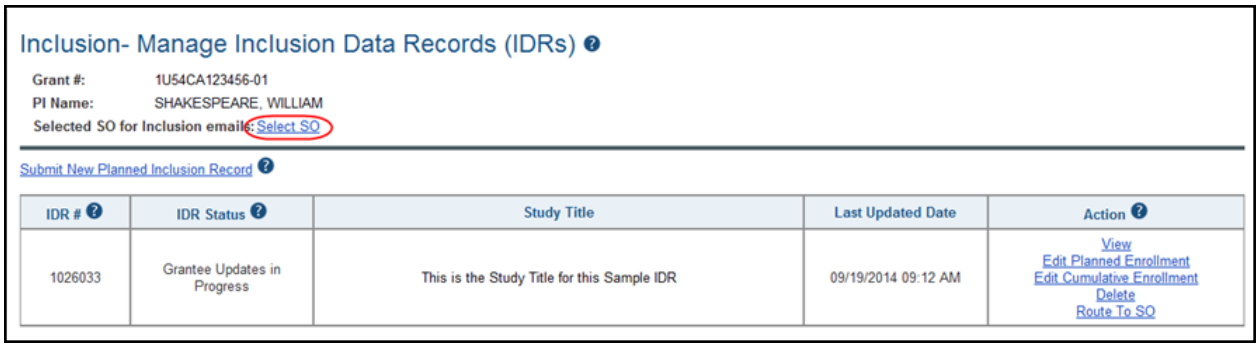
Principal Investigators (PI) (and delegates) must select a specific Signing Official (SO) to receive email notifications concerning the inclusion record(s).

NOTE: An SO has institutional authority to legally bind the institution in grants administration matters. The individual fulfilling this role may have any number of titles in the grantee organization. The label *Signing Official* is used in conjunction with the NIH eRA Commons. The SO can register the institution and create and modify the institutional profile and user accounts. The SO also can view all grants within the institution, including status and award information. An SO can create additional SO accounts as well as accounts with any other role or combination of roles. For most institutions, the Signing Official (SO) is located in its Office of Sponsored Research or equivalent.

For more information on the SO role, refer to the Commons Online Help.For more information on the SO role, refer to the Commons Online Help at https://era.nih.gov/erahelp/commons#Commons/roles/SO.htm.

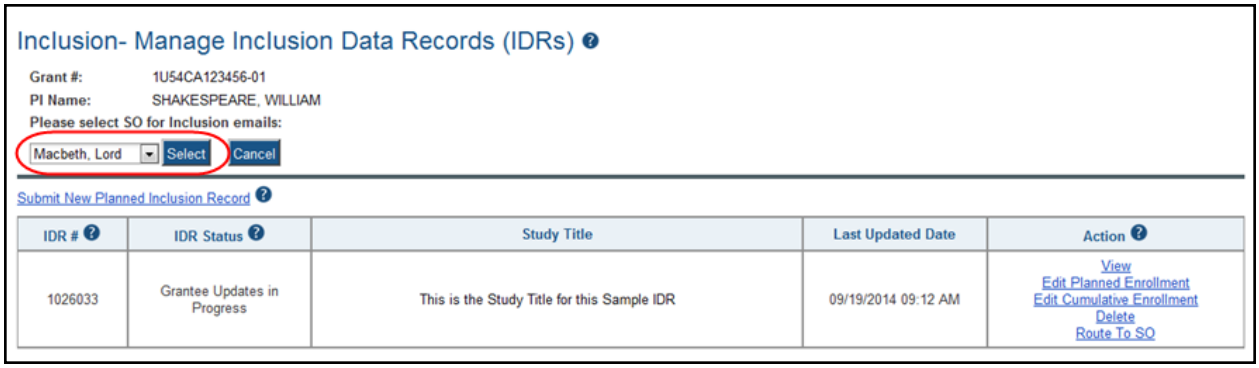
Follow the steps below to select an SO for inclusion emails.

1. From the *Inclusion – Manage Inclusion Data Records (IDRs)* screen, click the **Select SO** link. This link is located near the top of the screen under the grant and PI information.

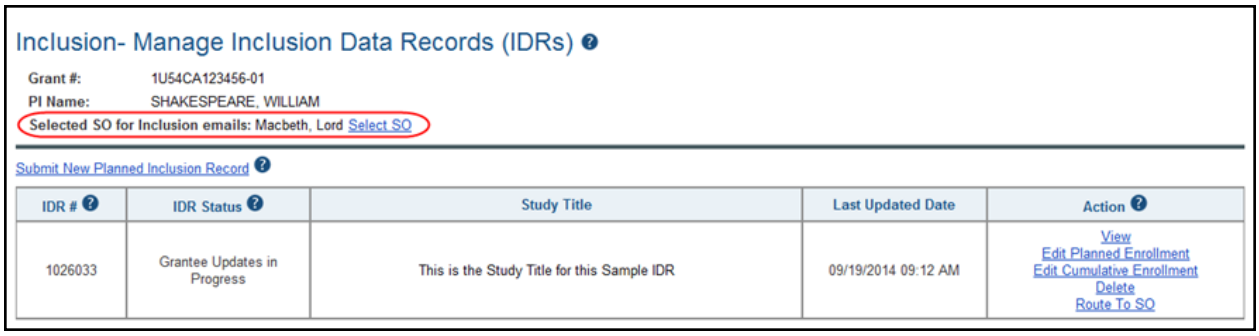


2. From the drop-down list presented on the screen, select the appropriate SO name.

3. With the name displayed in the box, click the **Select** button.



The screen updates to display the name of the SO next to the title **Selected SO for Inclusion emails**. The **Select SO** button remains available on the screen and can be used to choose a different SO.



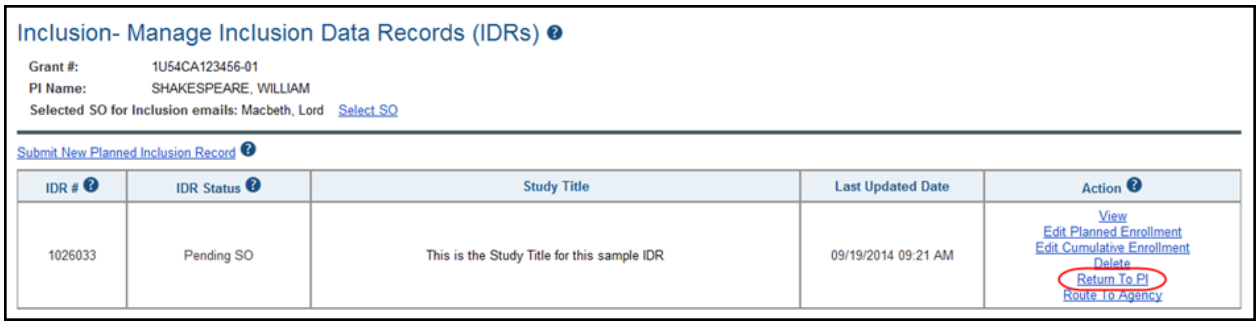
5.14 Return to PI

As the SO, after reviewing the inclusion data routed to you by the PI, you may find it necessary to return the IDR to the PI for further updates. This function is performed on the *Inclusion–Manage Inclusion Data Records (IDRs)* screen and is available to SO users when the IDR is in a status of *Pending SO*.

This function is only necessary if the IDR needs to be returned to the PI for purposes specific to your business process. If you need to submit the IDR to Agency, you are not required systemically to return the IDR to the PI. Instead, use the **Route to Agency** link.

To return the IDR to the PI:

1. Navigate to the *Inclusion–Manage Inclusion Data Records (IDRs)* screen.
2. Locate the IDR to route from the **Prospective Studies** hitlist.
3. Select the **Return to PI** link. The link will only display for IDRs in a status of *Pending SO*.



When returned to the PI, the following actions occur:

- Email notification is sent to the PI
- IDR status updates to *Grantee Updates in Progress*
- The action is recorded in the *Action History*

5.15 Route to Agency

SOs and PIs delegated with submit authority in eRA Commons can submit IDRs to Agency from the *Inclusion–Manage Inclusion Data Records (IDRs)* screen.

NOTE: The process of delegating authority to a PI to submit progress reports on behalf of an institution is performed in eRA Commons Admin module. For information on delegating *Progress Report* authority to a PI user, please refer to the *Commons Online Help* topic titled Delegating Progress Report Authority on Behalf of Another User.

To route the IDR to Agency:

1. Navigate to the *Inclusion–Manage Inclusion Data Records (IDRs)* screen. Refer to the topic titled *Access IMS as an SO* on Page xvi for details.

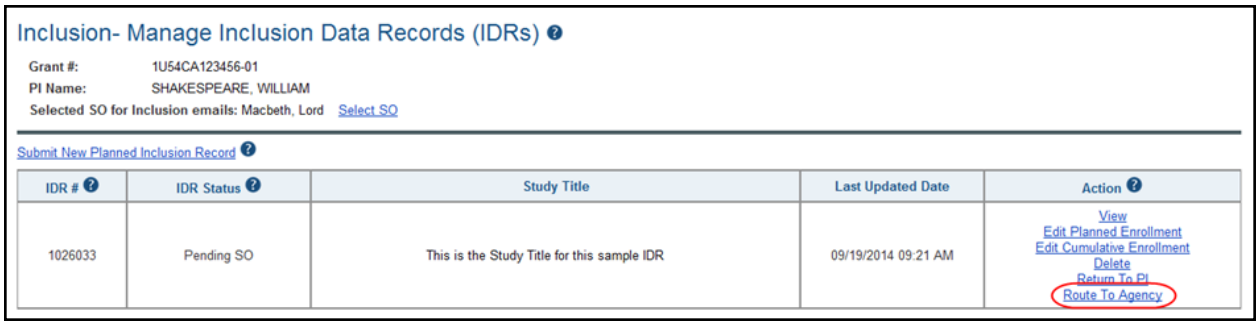
2. *Only Applicable to PIs Submitting the IDRs:* Verify that an SO name appears in the **Select SO for Inclusion Emails** field.

You must first choose an SO before submitting the IDR; IMS will send an email notification to the selected SO informing him/her that you have submitted the IDR. If an SO is not selected prior to submitting the IDR to Agency, you will see the following error: *Please select SO. Routing cannot be completed without selecting SO.*

If you're not sure which SO to select, contact your Institution's grants office. For more information, see *Select SO for Inclusion Emails* on Page xliii.

3. Locate the IDR to route from the **Prospective Studies** hitlist.

4. Select the **Route to Agency** link. The link will only display for IDRs in a status of *Grantee Updates in Progress* or *Pending SO*.



When routed to the Agency, the following actions occur:

- Email notification is sent to the Program Official (PO) assigned to the award. In the case of a subproject with no specific PO listed, the email is sent to the PO of the parent application.
- *Only When Submitted by the authorized PI:* Email notification is sent to the SO
- IDR status updates to *Received by Agency*
- The action is recorded in the *Action History*
- New version of IDR is created

5.16 Sample Notifications

Below are sample email notifications generated from IMS when routing occurs.

5.16.1 PI Has Routed an IDR to an SO

The following email notification is sent to the selected Signing Official when a PI (or delegate) has routed an IDR to that SO. PIs must select the appropriate SO from a list before routing can take place.

For information on routing IDRs to an SO, refer to the topic titled *Route to SO* on Page xlii.

From: eraNotifications@mail.nih.gov

Sent: <Date Time>

To: <SO email>

CC: <>

Subject Line: PI routed Inclusion Data for grant [parent GrantNumber], Inclusion Data Record# [IDR#]

PI routed Inclusion Data for:

• [parent GrantNumber] - [parent ProjectTitle].

• Inclusion Data Record (IDR) # - [IDR#]

• Study Title – [Study Title]

If you have any questions about this email, please contact <parent contact PI Name> at < parent contact pi email>, who initiated this action.

If you incur any problem while using the eRA Commons, please contact the eRA Service Desk at 1-866-504-9552 or commons@od.nih.gov.

*** This is an automated notification - Please do not reply to this message. ***

5.16.2 SO Has Returned an IDR to the PI

The following email notification is sent to the Contact PI when the Signing Official (SO) returns previously routed IDR.

For information on returning routed IDRs to PI, refer to the topic titled *Return to PI* on Page xliv.

From: eraNotifications@mail.nih.gov

Sent: <Date Time>

To: <parent contact pi email>

CC: <pi delegate(s) email>

Subject Line: SO returned Inclusion Data for grant [parent GrantNumber]

Dr. [parent Contact PD/PI Name],

SO returned Inclusion Data for:

• [parent GrantNumber] - [parent ProjectTitle].

• Inclusion Data Record (IDR) # - [IDR#]

• Study Title – [Study Title]

If you have any questions about this email, please contact your Program Officer, [PO Name] at [PO Email] or by phone at [PO Phone].

If you incur any problem while using the eRA Commons, please contact the eRA Service Desk at 1-866-504-9552 or commons@od.nih.gov.

5.16.3 A Delegated PI Has Submitted the IDR to Agency

Some PIs are delegated authority in eRA Commons to submit progress reports to the Agency on behalf of the SO and institution. These same delegated eRA Commons users have the ability to submit IDRs to Agency.

The following email is sent to the Signing Official when a delegated PI submits an IDR to Agency.

For information on routing IDRs to Agency, refer to the topic titled *Route to Agency* on Page xlv.

From: eraNotifications@mail.nih.gov

Sent: <Date Time>

To: < SO email>

CC: < >

Subject Line: PI routed Inclusion Data to Agency for grant [parent GrantNumber], Inclusion Data Record# [IDR#]

PI routed Inclusion Data to Agency for:

• [parent GrantNumber] - [parent ProjectTitle].

• Inclusion Data Record (IDR) # - [IDR#]

• Study Title – [Study Title]

If you have any questions about this email, please contact <PI Name> at <pi email>, who initiated this action.

If you incur any problem while using the eRA Commons, please contact the eRA Service Desk at 1-866-504-9552 or commons@od.nih.gov.

5 Inclusion Data Record Statuses

Throughout the process from creation to submission to Agency, an inclusion data record will take on various statuses depending on the action completed against it. These different statuses aid in determining the current point in the work flow, pending needs and requirements, and past actions taken. An IDRs status also determines what action(s) can be performed against it. IDRs requiring updates can be edited, while IDRs accepted by the Agency can only be viewed.

The following list gives an explanation of each status.

Accepted – Not Rolled Forward: The IDR is either marked as Not Funded or as Type 2 Progress Report. The project is awarded, but the IDR is not rolled forward into an out year record.

Accepted: The IDR has been accepted at award issuance based on what was originally submitted. (Data migrated from the previous data system may also have this status when awarded.)

Grantee Updates in Progress: Grantee user has created the IDR; Grantee user has initiated updates on an IDR (Edit Planned or Edit Cumulative); and/or SO has routed an IDR back to the PI

Inclusion Updated: Grantee has updated cumulative (actual) enrollment counts via the RPPR module in Commons

Previous Data: Data from previous fiscal year has been rolled forward into the next project record

Pending SO: IDR has been routed to the Signing Official (SO)

Received by Agency: IDR form (Planned or Cumulative) has been received as part of the electronic application submission (i.e., Grants.gov/eSub or ASSIST); Grantee user (SO) has routed the IDR via IMS in the Commons Status module to the Agency; Agency user has created a new IDR in IMS; IDR is inserted or updated via web service. This applies to intramural projects and certain contracts.

Received by Agency – RPPR: Grantee user submitted IDR to Agency as part of the Research Performance Progress Report (RPPR)

6 Glossary

A

Agency
The organization responsible for administering a grant via eRA modules. Agency may refer to NIH or one of the partnering HHS Operating Divisions (see OpDiv).

Appl ID
The unique, system identifier number assigned to an application.

E

eRA
Electronic Research Administration. The NIH's infrastructure for conducting interactive electronic transactions for the receipt, review, monitoring, and administration of NIH grant awards to biomedical and behavioral investigators worldwide. May also refer to the group responsible for this infrastructure.

Error
A message displayed by the system to show that action must be taken before further processing can continue. An error represents a 'hard stop' in the system.

Existing Data Set (or Resource)
An existing dataset may be constructed of different types of data including but not limited to survey data, demographic information, health information, genomic information, etc. Also included would be data to be derived from existing samples of cells, tissues, or other types of materials that may have been previously collected for a different purpose or research question but will now be used to answer a new research question. In general, these will be studies meeting the NIH definition for clinical research with a prospective plan to analyze existing data and/or derive data from an existing resource and where no ongoing or future contact with participants is anticipated.

F

FOA
A publicly available document by which a Federal Agency makes known its intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds. Funding opportunity announcements may be known as program announcements, requests for applications, notices of funding availability, solicitations, or other names depending on the Agency and type of program.

Foreign/Domestic Indicator

Indicates whether the IDR involves participants from a non-US site (i.e., foreign) or a US site (i.e., domestic). It is a required attribute for an IDR.

FY

Fiscal Year

G

Grant Folder

The official repository of grant-related documents and reports, which includes Summary Statements, Notice of Award (NoA), electronic Streamlined Non-Competing Award Process (eSNAP) Reports, and other grant-related information.

GUM

Grants Update Module

H

HS

Also Human Subjects Code. Code that reflects the status of human subjects inclusion catetegories on summary statements of grant applications and on the grants management and program officer worksheets.

Human Subject

A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information. Regulations governing the use of human subjects in research extend to use of human organs, tissues, and body fluids from identifiable individuals as human subjects and to graphic, written, or recorded information derived from such individuals.

I

IC

Institute/Center. The NIH organizational component responsible for a particular grant program or set of activities.

IDR

Inclusion Data Record

IDR

Also, IDR number. The IDR# is the unique Inclusion Management System-generated identifier for the inclusion data record (IDR). This number remains unchanged throughout the lifetime of the grant.

IDR IC ID

The IDR IC ID is an identification number entered by Agency staff as one of the optional IDR attributes. This value is not the same as the system-generated IDR #. This field could be blank if an IDR IC ID number was not assigned.

IMS

Inclusion Management System

IOPW

The Inclusion Operating Procedures Workgroup (IOPW) is a trans-NIH group of staff members involved in managing policies and procedures for inclusion monitoring at the ICs. These individuals are the primary points of contact at each IC. The roster can be obtained at the following site: http://nih-extramural-intranet.od.nih.gov/d/nih/committees/iopw/iopw.htm. <<MEREDITH: I cannot format text in the Flare glossary feature, this includes creating hyperlinks. Sorry.>>

L

Last Budget Period IDR

IDRs created by the Grantee for reporting changes in enrollment data or newly started studies for the research performed during the period of time between award of the last support year and the end of the project period. There are two types of Last Budget Period IDR: 1) those associated with a regular IDR and reflect updated enrollment and 2) those newly created that are not associated with a regular IDR.

N

NCT No.

Also, National Clinical Trial number. This unique number is also referred to as the ClinicalTrials.gov registry number. The format for the number is NCT followed by an 8-digit number (e.g., NCT12345678).

NIH

National Institutes of Health. A Federal agency whose mission is to improve the health of the people of the United States. NIH is a part of the Public Health Service, which is part of the U.S. Department of Health and Human Services.

No Planned Enrollment Reason

Indication why there is no planned enrollment data for the Inclusion Data Record (i.e., planned enrollment counts are equal to zero).

O

OpDiv

Operating Division. A HHS Operating Division is an agency that provides services to carry out the HHS mission. NIH's electronic Research Administration (eRA) currently partners with the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Substance Abuse & Mental Health Services Administration (SAMHSA), and the Department of Veterans Affairs (VA) to provide electronic grants management processing.

P

PCC

Program Class Code. The internal code, unique to each IC, indicating that IC's scientific interest. It is used to identify internal programs, branch classifications, the science or disease area, and sometimes program officials.

PHS

Public Health Service. Umbrella organization in the U.S. Federal Government consisting of eight HHS health Agencies, the Office of Public Health and Science, and the Commissioned Corps (a uniformed service of more than 6,000 health professionals). The NIH is the largest Agency within the PHS.

PO (PO name)

Program Official. The NIH official responsible for the programmatic, scientific, and/or technical aspects of a grant.

S

SMS

Subproject Management System

U

User Role

(sometimes, Role). A specific set of permissions assigned to a system user to set the limitations of that user's available system functions and features.

W

Warning

An informational message displayed by the system to show that an item or issue should be reviewed and verified before continuing the process. An warning is informational only and does not represent a 'hard stop' in the system.